In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-930V

(to be published)

KIRA HUGHES,	*	Chief Special Master Corcoran
Petitioner,	*	
v.	*	Filed: January 4, 2021
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal without hearing; HPV vaccine; POTS; Chronic Regional Pain Syndrome; Expert qualifications; Causation
Respondent.	*	

Braden Blumenstiel, DuPont and Blumenstiel LLC, Dublin, OH, for Petitioner.

Kyle Pozza, U.S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On August 3, 2016, Patrice Moczek filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"[2]), on behalf of her then-minor daughter, Kira Hughes. (Ms. Hughes became the Petitioner after she turned 18). In the Petition, Ms. Hughes alleges that the human papillomavirus ("HPV"), meningococcal, and tetanus diphtheria-acellular-pertussis ("Tdap") vaccines that she received on August 15, 2013, caused her

[1] This Decision will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

to suffer from leg pain, headaches, and fatigue, among other things. *See* Petition ("Pet.") at 1. She has since refined her claim, arguing that she experienced complex regional pain syndrome ("CRPS") and/or postural orthostatic tachycardia syndrome ("POTS") specifically due to the HPV vaccine. *See* Petitioner's Response to Respondent's Motion for Order to Show Cause, filed on Jan. 13, 2020 (ECF No. 75) at 5, 7.

After appellate practice occasioned by Petitioner's failure to meet scheduling deadlines was resolved, and then some intervening back-and-forth between the parties, I invited Respondent to seek dismissal of the case based solely on the filed record and expert reports. Motion for Ruling on Record, dated May 7, 2020 (ECF No. 81) ("Mot."). Petitioner has reacted to the motion, making it now ripe for resolution. Petitioner's Memorandum Contra to Respondent's Motion for Ruling on The Record, dated August 21, 2020 (ECF No. 86) ("Opp.").

Although Respondent moves for dismissal of this case without ever having filed any expert reports of his own, I find his motion is well-taken and appropriately granted. As discussed in greater detail below, even after the filing of multiple expert reports, Petitioner cannot meet her preponderant burden of proof, making a hearing unnecessary. The present record does not allow the conclusion that it is more likely than not the nonspecific symptoms she did experience (certain of her alleged injuries, such as POTS and CRPS, are *not* bulwarked with preponderant evidence) were vaccine-caused—or that the HPV vaccine *could* cause them. I have now repeatedly heard claims arguing that the HPV vaccine causes a variety of similar injuries, and no arguments made herein were any more persuasive, or reliably established, than those prior cases in which I (similarly) denied entitlement. Indeed—the experts offered to substantiate Petitioner's theory herein were especially unpersuasive or unqualified to offer the opinions they embraced.

I. Medical History

Relevant Pre-Vaccination Events

Ms. Hughes (who was close to 13 years old when she received the vaccines at issue) had some prior medical history events bearing on her claim. Ms. Hughes reports previously experiencing (among other things) ovarian cysts, heavy menses, occasional back pain, and multiple urinary tract infections ("UTI"). Ex 1 at 6. She also had some emergency treater visits that parallel certain of her post-vaccination treatment incidents. For example, on November 27, 2012 (approximately nine months prior to the vaccinations in question), Petitioner was seen at Wheeling Hospital in Wheeling, West Virginia, for "problems with breathing, high heart rate, SOB [shortness of breath], dizzy feeling," and she reported at this time a family history of anxiety (which treaters settled on as explanatory after a normal EKG). Ex. 2 at 5.

A month later, on December 10, 2012, Ms. Hughes saw a physician's assistant at Clay-Battelle Community Health Center in Blacksville, West Virginia, complaining of three days of dizziness, two weeks of headache, and heavy menstrual periods for two months. Ex 1 at 20. Blood

testing, however, produced normal results, and Petitioner was assessed only with general "dizziness," which was thought possibly to be the product of an inner ear or optical issue. *Id*. at 19, 22. Then, on January 4, 2013, Petitioner went to a different treater, reporting bruising following a fall and associated knee pain. The history indicated that patient had a left patella subluxation which spontaneously reduced one-to-two years prior, and she was referred for physical therapy in association with this knee problem. Ex. 1 at 15–16.

Vaccinations and Purported Symptoms Onset

On August 15, 2013, Petitioner went back to the physician's assistant she had seen in December 2012 at Clay-Battelle Community Health Center for "immunization need." Ex. 1 at 6. The medical record of this visit indicated a history of "migraines." *Id*. Ms. Hughes received the Meningococcal, Tdap, and HPV vaccines that she alleges were causal of her subsequent medical issues. *Id*. at 7. There is no evidence in the record of any immediate reaction to these vaccines—although within a week of their receipt, Petitioner returned to Clay-Battelle Community Health Center on August 21, 2013, with "complaints of a urinary tract infection," along with purported flank pain and occasional nausea for the prior two days. Ex. 1 at 4. On exam, she displayed mild generalized abdominal tenderness, but her lower extremities were described as not tender, and she largely appeared to be comfortable and pain-free. *Id.* at 3. Based on the conclusion that she was experiencing another UTI, Ms. Hughes was prescribed an antibiotic and underwent a urine culture that subsequently came back negative. *Id.* at 5.

Two days later (now eight days post-vaccination), on August 23, 2013, Petitioner was seen by Cynthia Walsh, M.D. (an obstetrics and gynecology specialist) for unspecified lower abdominal pain that she reported had begun four days prior, adding that her menses had started the day before vaccination and was still causing some spotting. Ex. 24 at 8. Her exam was unremarkable (including a pelvic ultrasound, which ruled out another cyst as explanatory), and the assessment merely noted that Ms. Hughes had (within a period of days) twice reported abdominal pain during menses. *Id.* at 9. The following month (September 2013), she returned to Dr. Walsh and was assessed with dysmenorrhea (cramping and pain associated with menstruation) and prescribed a low-dose oral contraceptive to help limit the symptoms. *Id.* at 6–7.

October 2013 Symptoms

Ms. Hughes's treatments and emergency care doctor's visits greatly increased in October 2013, although even by this time (seven to nine weeks post-vaccination) no medical professionals had proposed any connection between her symptoms and the vaccines she had received nearly two months prior. Petitioner alleges, however, that immediately following receipt of the HPV vaccine in August 2013, she experienced pain in her arm that was so severe that once she got

home, she felt like she was going to pass out. Affidavit of Kira Hughes at 2, filed on Jan. 26, 2018 as Ex. 46 (ECF No. 54-4) ("First Hughes Aff."). She described her arm as "swelled [sic] and [] mottled," and recalls crying for four hours straight because of pain. First Hughes Aff. at 2. Petitioner's mother also alleges that Ms. Hughes experienced very similar immediate symptoms to what Petitioner described, adding that soon after vaccination, her daughter also began complaining of severe abdominal pain and back pain. Affidavit of Patrice Moczek at 3, filed on Jan. 26, 2018 as Ex. 45 (ECF No. 54-4) ("Moczek Aff."). Ms. Moczek goes on to allege that over the next few weeks (following vaccination), her daughter's "symptoms progress[ed] and she became mostly bedridden with pain and fatigue." Moczek Aff. at 3. She added that "[i]t seemed every other day a new symptom was being added to the myriad already existing." *Id.* As already noted, however, the contemporaneous medical record does not corroborate these contentions (although it does reveal Petitioner reported abdominal pain deemed by treaters to be associated either with a UTI or menses).

On October 16, 2013, Petitioner returned to Dr. Walsh, now complaining of bilateral "leg pain," which she stated had begun three days before. Ex. 24 at 3. To assess a possible etiology for this pain, it was proposed that Petitioner undergo a Doppler study of her lower legs (*Id.*)—but the study revealed no evidence of any deep vein thrombosis. *Id.* at 5; Ex. 4 at 4. Two days after (October 18, 2013), however, Ms. Hughes went to the Monongalia General Hospital emergency department in Morgantown, West Virginia, reporting "leg cramping since the weekend," as well as headache and back pain. Ex. 7B at 16. But after all testing and x-ray imaging produced normal results, her treaters proposed that her symptoms were attributable to "myalgia; growing pains," and it was recommended that she receive an over-the-counter pain medication. *Id*. at 20.

Petitioner continued thereafter to report ongoing symptoms similar to those she had complained of at these two care visits. A few days after her ER visit, Ms. Hughes was seen by Joseph Li, M.D., on October 22, 2013, reporting leg pain for ten days. Ex. 3 at 5. She specifically described the pain as worse in the morning, associated at times with limping, and although it could occur in her back was generally more intense in her legs. *Id.* She denied, however, any associated weakness, numbness, or sensation changes, and also reported that she had ceased taking the contraceptive that Dr. Walsh had prescribed. On exam, Petitioner reported tenderness in her lower extremities when touched, and testing revealed slightly elevated muscle enzyme levels (which could be suggestive of muscle injury),[3] but she tested negative for Lyme disease and revealed a normal rheumatoid factor. *Id*. at 8; Ex. 7B at 7–11. Ms. Hughes was diagnosed with a nonspecific myalgia, and prescribed a muscle relaxant. Ex. 3 at 9.

[3] Aldolase, a muscle enzyme, is used in the glycolytic breakdown of glucose. *Mosby's Manual of Diagnostic and Laboratory Tests* 41 (6th ed. 2018). Elevated aldolase levels are seen in patients with primary muscular disorders, and thus testing for it is useful for identifying muscular or hepatic cellular injury or destruction. *Id.*

A week later, on October 29, 2013, Petitioner saw another treater on referral from Dr. Li for the recent leg pain she had been experiencing that month. Ex. 6A at 4. She reported that the pain was worse with walking, her left leg was weaker than her right, but that her ER visit had produced a "growing pains" diagnosis. *Id*. at 8.[4] Petitioner underwent a CT scan of her lumbar spine, plus more lab testing, but all results were normal. *Id*. at 14–15. In addition, a physical exam revealed inconsistent results, with "indirect" observation of the Petitioner (in terms of strength, sensation, and range of motion) suggesting less problems than when she was directly being examined. *Id*. at 8. Indeed, the physician treater also noted in the record from this visit that Ms. Hughes generally seemed cheerful and unconcerned by the complained-of problems. *Id*. Thus, although evaluating treaters who saw Petitioner at this visit initially proposed that Petitioner's leg pain complaints could be a function of a neurologic or musculoskeletal disorder, it was ultimately concluded that her inconsistent complaints made it difficult to identify a proper diagnosis. *Id*. at 6, 9.[5] As a result, treaters decided to admit Petitioner for further evaluation and testing. *Id*. at 15.

On October 29, 2013, Ms. Hughes was admitted to the West Virginia University Hospital in Morgantown, West Virginia, by Jeffrey Lancaster, M.D. Ex. 6A at 11. On exam, she again revealed multiple areas of abdominal, back, and lower extremity tenderness, leading treaters to characterize her presentation as "multiple vague complaints," with no evidence of an acute inflammatory disorder that might explain her symptoms. It was noted that Petitioner's symptoms might qualify as fibromyalgia, but treaters added that her young age made that diagnosis unlikely. *Id*. at 15. The records from this admission also indicate that Ms. Moczek again speculated that Petitioner's receipt of the HPV vaccine explained her symptoms, although treaters pushed back against that supposition. Ex. 6A at 16, 19.

In the course of Petitioner's hospitalization, a variety of diagnostic possibilities were explored. Inflammatory myopathy and malignancy were ruled out, along with an Epstein-Barr viral infection or Lyme disease (given negative testing results), and although a post-viral myalgia syndrome was deemed possible, it was considered difficult to confirm by testing. Ex 6A at 23. Hospital treaters again gave no credence to the possibility (raised by Ms. Moczek) that the HPV vaccine might be causal, urging Petitioner's family instead to consider a brain MRI to rule out multiple sclerosis (a proposal the family initially rejected). *Id*. at 23, 26–27. Anxiety, however,

[4] In addition, Ms. Moczek informed the treater at this time of her nascent view that Ms. Hughes's symptoms had begun after, and were possibly associated with, her receipt of the HPV vaccine in August earlier that year. Ex. 6A at 4.

[5] During this October 29, 2013 emergency room visit, Petitioner was seen by multiple treaters who had slightly varying opinions. *See* Ex. 6A at 3-16. Treater Monica Shaffer's recorded impression, for example, was of concern for musculoskeletal disorder, neurological disorder, or other etiology. *Id*. at 5. An attending note by Dr. Anna Marie Scott said that Petitioner had already been seen by multiple physicians, was referred here for pediatric neurology, and that inconsistent exam made differential difficult. *Id*. at 8. And Dr. Jeffrey Lancaster (the physician who ultimately admitted Petitioner to the hospital) raised the possibility of fibromyalgia. *Id*. at 14.

was given a "high likelihood" as explanatory, in light of the nonspecific overall nature of Petitioner's complaints and the lack of objective lab or exam findings that would substantiate them. *Id.* at 23, 27.

On October 31, 2013, Ms. Hughes had a consultation with neurologist Jodi Lindsey, M.D., to rule out a neurologic etiology for her complaints. Petitioner summarized for Dr. Lindsay her overall course of symptoms (leg and back pain, fatigue, headaches, jaw pain, constipation, bad menstrual cramps, night sweats, dizziness/tunnel vision when getting up too fast, etc.), and Ms. Moczek repeated her suspicions regarding the HPV vaccine. Ex. 6A at 28.[6] On exam, Ms. Hughes had "giveaway weakness" in her left lower extremity, with slight hyperreflexia in the lower extremities as well. *Id*. at 29. The assessment was "[n]o true weakness but give-away weakness" and "[m]ajority of symptoms might be related to chronic constipation." *Id*. at 32. Dr. Lindsey ordered an MRI of the lumbar spine, but it showed only some minor disc bulging deemed unlikely to cause her symptoms, and all other lab testing produced "unremarkable" results. *Id*. at 24, 33.

Petitioner was discharged on November 1, 2013. Ex. 6A at 36. Dr. Lancaster's discharge summary observed that there was "no clear etiology" for Petitioner's complained-of symptoms, given that the entirety of her work-up (which included evaluations for neuropathic, rheumatologic, malignant and musculoskeletal causes) had produced normal findings. *Id.* Anxiety was again proposed as possibly explanatory—despite rejection of that diagnosis by Ms. Hughes's family, and their continued view that her symptoms instead arose from the HPV vaccine. *Id*. A brain MRI was once again recommended. *Id.* On November 4, 2013, Ms. Hughes underwent a brain and spine MRI which were "[a]ll normal except the MRI of the spine read as subtle loss of height of disc space at L4-5 level." Ex. 3 at 11.

About a week after her discharge, on November 6, 2013, Ms. Hughes went back to Dr. Li for a follow-up. Dr. Li's history from this visit notes the "[g]eneral consensus" that no physical explanation for Petitioner's symptoms had been identified. Ex. 3 at 16. Dr. Li, however, specifically observed at this time disparities between Petitioner's complained-of symptoms and her conduct during the exam. For example, Ms. Hughes moved "without difficulties" while in Dr. Li's office, although on departure "her gait was unsteady and stiff when she left." *Id.* at 13. In addition, in order to be examined she easily removed her tightly-fitting jeans with no reaction or

[6] A November 1, 2013, a spiritual care note from Kristen Taylor of West Virginia University Hospitals indicates that Petitioner's family expressed frustration that their concerns about the HPV vaccine's possible role in her symptoms (especially given their ambiguity) were not being taken seriously by treaters, noting that based on their own research, "every one of [Petitioner's] symptoms matches up with these bad reactions," and setting forth their intent to pursue the matter independently once Petitioner was discharged. Ex. 6A at 83, 84.

expressions of pain to her legs, yet in response to light touching associated with Dr. Li's exam she expressed severe pain—then clothing herself thereafter with no apparent discomfort. *Id*.[7]

At this time, Petitioner otherwise continued to complain of symptoms comparable to what she had previously reported, including "malaise and anorexia," gastrointestinal "cramping," "myalgias and stiffness," "weakness," mild back pain, and anxiety associated with the aforementioned symptoms. Ex. 3 at 12. Dr. Li offered the possibility that "somatization disorder"[8] might explain Petitioner's symptoms. *Id*. at 12, 16. In response, Ms. Moczek asked again about whether the HPV vaccine could explain Petitioner's symptom—a proposal Dr. Li rejected, although he did not oppose Petitioner obtaining treatment from a practitioner of holistic medicine. *Id*.

Treatment in 2014

In 2014, Petitioner and her family continued to seek an explanation for her constellation of symptoms. The record from the time reveals additional physician determinations that Ms. Hughes's complaints were more likely attributable to a mental/cognitive problem—but also that Petitioner and her family rejected such assessments, in favor of her family's preferred view that the HPV vaccine explained her symptoms, and that treaters of questionable competence were sought to confirm that view.

Thus, on January 7, 2014, Petitioner had an outpatient neurology follow-up visit with Dr. Lindsey, at which time all her hospitalization testing results (which had produced normal results), plus the post-hospital assessment of anxiety, were considered in light of her ongoing complaints. Ex. 6C at 29. As before, Ms. Hughes and Ms. Moczek expressed their belief that Petitioner's symptoms were the product of "an inflammatory process ongoing triggered by the administration of the [HPV] vaccine," and that her prior symptoms of headache, leg pain, etc. continued, although these symptoms were alleviated by a diet recommended by a naturalist and other vitamin supplements. *Id*.

Dr. Lindsey performed a neurologic exam which produced normal results and again noted "no clear evidence for a myopathy or neuropathy," as well as a lack of evidence of an

[7] Dr. Li's notes also mention Ms. Hughes's stay-at-home status as of the beginning of November 2013 (since she now had reportedly missed three weeks of school due to her symptoms). Ex. 3 at 16. In response to Dr. Li's comments that Petitioner could go back to school if she got better, she cried, objecting that she was "not pretending to be sick." *Id*. at 15. She also denied that her symptoms were the product of anxiety about school problems, but objected when Dr. Li discussed "the possibility of somatization/conversion of her symptoms." *Id*. at 11.

[8] Somatization disorder is a mental disorder characterized by multiple somatic complaints that cannot be fully explained by any known general medical condition or the direct effect of a substance, but are not intentionally feigned or produced, beginning before the age of 30 and occurring over several years. Somatization disorder, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=71227&searchterm=somatization+disorder (last visited October 20, 2020). Complaints comprise a combination of at least multiple pain symptoms, multiple gastrointestinal symptoms, a sexual symptom, and a neurologic symptom. *Id*. They are often presented in a dramatic, vague, or exaggerated way, with involvement of numerous physicians, numerous diagnostic evaluations, and unnecessary medical treatment or surgery. *Id*.

existing/ongoing inflammatory process. Ex. 6C at 32. Dr. Lindsey did not feel an EMG was warranted, questioned Ms. Moczek's contentions about the role the HPV vaccine had played, and (like Dr. Li) proposed that treatment for somatization disorder was more appropriate. *Id.* Dr. Lindsey also disputed that Petitioner revealed any clinical indicia characteristic of CRPS, and suggested a management protocol to assist Ms. Hughes with headaches. *Id*.

Around the start of 2014 Ms. Hughes also began to see Dr. Phillip DeMio—a purported specialist in treatment of Lyme disease and autism, and one of her three experts in this case—at Whole Health & Wellness in Worthington, Ohio.[9] *See generally* Ex. 10A. The December 2013 intake form (which, like many of the records associated with Dr. DeMio is in scribbled handwriting that is virtually impossible to decipher) indicates that Petitioner was experiencing myalgias, headaches, and constipation, and provided some of her history (including receipt of the HPV vaccine). *Id.* at 2–3. Dr. DeMio also noted Ms. Moczek's claim that Petitioner had an "uneven smile" that could be suggestive of a "mild Bell palsy on the left side of her face." *Id.* at 4. Dr. DeMio started the Petitioner on several vitamin and mineral supplements, and ordered several labs to test for infection, metabolic disorders, hormone imbalance, myositis, heavy metal toxicity and immunodeficiency.

Two months later, on March 19, 2014, Petitioner returned to Dr. Li, continuing to complain of persistent pain that she reported began in October 2013 (two months after the vaccinations at issue). Ex. 3 at 18. Ms. Moczek informed Dr. Li that Dr. DeMio had proposed that Petitioner might have some kind of Lyme disease (although Dr. Li observed in response that his own testing had been negative for Lyme disease) *Id*. Petitioner's family also requested a referral to a rheumatologist.

In reaction, and consistent with his observations from November 2013, Dr. Li again noted the disparity between the persistent pain reported by Petitioner and her seemingly healthy demeanor and conduct during the exam. Ex. 3 at 22. Dr. Li also attempted to reaffirm to Petitioner's family that the sum total of his prior work-up for Ms. Hughes was negative, and that he did not see the need for the testing that Dr. DeMio had requested. *Id.* Diagnoses proposed by Dr. Li after this visit included myalgia and somatization disorder, and he indicated that he would refer Petitioner to a rheumatologist, although if such a specialist could not identify an explanation for the complained course of symptoms, "then we really have to focus on getting her psychiatric help." *Id*. at 24.

On March 31, 2014, Ms. Hughes was seen in an adolescent medicine clinic at West Virginia University Hospital by Ahmad Al-Huniti, MD for chronic pain in her back, legs, and shoulders, plus headaches, fatigue, and sleep interference at night (which in turn was causing her sleepiness during the day). Ex. 6C at 205–12. Her 2014 visits to "Lyme specialist" Dr. DeMio were noted. *Id.* at 207. Dr. Al-Huniti's assessment recorded the presence of "multiple complaints

[9] Dr. DeMio's website states that his practice focuses on medical testing and treatment for autism, AD/HD disorders, and Lyme disease. *See* About Dr. DeMio, http://drdemio.com/dr-phillip-demio/ (last visited on October 20, 2020).

without clear etiology," which he proposed "could be psychogenic or related to complex regional pain syndrome, chronic fatigue syndrome, Ehlers-Danlos/POTS," while also allowing that a mental health origin could also be explanatory. *Id*. at 211. Dr. Al-Huniti proposed follow-up in three weeks, but it is not evident from the record that this occurred.

On April 22, 2014, Ms. Hughes had her initial rheumatology evaluation at Nationwide Children's Hospital in Columbus, OH, by Bethanne Thomas, CPNP and Sharon Bout-Tabaku, M.D. for "chronic fatigue and generalized pain". Ex. 5 at 6. The HPV vaccine was again reported by Petitioner and her family to have initiated Petitioner's symptoms, although at this visit Ms. Moczek described a more immediate onset of pain in August 2013, despite a lack of prior record support for such assertions. *Id*. Treater impressions were benign hypermobility syndrome, amplified musculoskeletal pain, and fatigue, and they recommended desensitization by massaging areas of pain to help retrain her overstimulated nervous system. *Id*. at 67-68. They noted that joint hypermobility as well as psychological factors can increase the risk of developing amplified musculoskeletal pain, however, and thus also suggested treatment for anxiety. *Id*.

In the meantime, Petitioner underwent the testing proposed by Dr. DeMio, obtaining the results at the end of April 2014. Ex. 10B at 13–69. Such testing resulted in normal thyroid studies (including negative thyroglobulin antibody), no evidence of Lyme disease, and negative serologies for cytomegalovirus. *Id*. at 28–32. Other studies, however, revealed elevated Mycoplasma IgG and IgM antibodies, which were deemed suggestive of a current (reflected in the IgM findings) or prior/resolved (for IgG) infection, with the IgG levels specifically positive for Human Herpesvirus-6, although numerous other infectious diseases were ruled out. *Id*. at 33–34, 35–51.[10] In addition, no MTHFR mutation was observed, and Petitioner's estrogen/testosterone levels were normal. *Id*. at 43.

In early May 2014, Ms. Hughes was seen in a genetics clinic at West Virginia University Hospital by Tara Narumanchi, M.D. for "joint hypermobility and chronic pain" and assessment for any possible genetic etiology. *See generally* Ex. 6C at 222–27. But following examination, Dr. Narumanchi proposed that there was no need for further testing. Instead, she recommended physical therapy (hydrotherapy), plus a pediatric cardiology evaluation with a tilt table test "due to concern of POTS," although is not evident from this record (other than Petitioner's mother expressing concern to treaters) why POTS was considered at all (beyond the fact that POTS had

[10] "Immunoglobulin G (IgG) and Immunoglobulin M (IgM) are antibodies produced in response to infection, and their titer levels can help monitor or detect immune deficiencies. IgM is an indicator of current infection, while IgG reflects exposure to a past infection. Increased levels of IgG or IgM are indicia of hepatic diseases (including connective tissue diseases and acute/chronic infections), while decreased levels are found in patients with primary/secondary immune deficiencies." *See Knorr v. Sec. of Health & Human Servs.*, No. 15-1169V, 2018 WL 6991548, at *34 n.7 (Fed. Cl. Spec. Mstr. Dec. 7, 2018) (citing *Immunoglobulins (IgG, IgA, and IgM), Serum*, Mayo Clinic Med. Laboratories, https://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8156 (last accessed June 14, 2018)).

come up in Dr. Al-Huniti's evaluation from March 2014). *Id.* at 225.[11] Later on that same month, in mid-May 2014, Ms. Hughes was treated at Ohio Valley Medical Center emergency room for abdominal pain and vomiting. Ex. 8 at 4. An X-ray revealed large fecal material and Petitioner was given an enema, relieving the pain. *Id.* at 7. No explanation was offered for the incident that would conceivably relate it to Petitioner's purported HPV-caused symptoms. *Id.* at 3–4.

Additionally, on June 25, 2014, Petitioner had an initial evaluation by Dr. Freeda Flynn in Saint Clairsville, Ohio for reported "HPV Complications." Ex. 23 at 18.[12] The differential diagnosis included mycoplasma (acute), HSV-6 and possible HPV reaction, but Dr. Flynn's handwritten assessment was solely "headaches, rash, palpitations" with a notation suggestive of her conclusion that Petitioner should obtain an evaluation from a pediatric cardiologist. *Id.* at 20. *Id.* Ms. Hughes was prescribed Vitamin C, magnesium supplements, and an antibiotic. *Id.* Petitioner followed up with Dr. Flynn on August 22, 2014. *Id.* at 14. Her physical exam revealed muscle tenderness at what Dr. Flynn deemed "fibromyalgia trigger points"(*Id.* at 17). And Dr. Flynn's assessment was consistent with the past, but also added "reaction to Gardasil [HPV]," although the records from this visit contain no explanation for the basis for that determination. *Id.*

Toward the fall of 2014, Petitioner continued to obtain more treatment from those providers whose assessments were consistent with the views of her family regarding the role the HPV vaccine played in her symptoms, with no evidence of further treatment from those providers who did not so conclude. For example, Dr. DeMio prescribed pain medication in late September 2014 to Petitioner, although she did not take it due to fears of nausea side effects. Ex. 17 at 9. In a follow-up visit, she described intense pain after attempting to return to school. *Id.* at 14. Dr. DeMio opined that it was still possible (despite negative results) that Ms. Hughes had Lyme disease, and for treatment he prepared a 19-item list, featuring numerous supplements, antivirals, and antibiotics. *Id.* at 17.

That same month, Dr. Flynn prepared a "To-Whom-It-May-Concern" letter stating that Ms. Hughes was being "treated for a mycoplasma infection and Gardesil [sic] Syndrome. It is in her best interest to remain home bound from August 19-December 19." Ex. 23 at 27. And in mid-September 2014, Petitioner went to the Wheeling Hospital emergency room complaining

[11] This record also references a letter attachment (Ex. 6C at 225), in which it can be presumed that Dr. Narumanchi expanded on the bases for her conclusions, but the letter itself does not appear to have been filed.

[12] It is not self-evident why Dr. Flynn was consulted to assist with Petitioner's treatment. Somewhat bearing on the credibility of her medical assessment, however, is the fact that her practice was raided by the U.S. Drug Enforcement Agency in 2019 for suspicion of Medicare fraud, and Dr. Flynn was charged with eight counts of distribution of controlled substances, and one count of health care fraud for her alleged participation in the unlawful prescription of controlled substances outside of the course of professional practice and without a legitimate medical purpose, and health care fraud for the submission of claims for services which were medically unnecessary and/or performed below medically-accepted standards. *See* Press Release, The United States Department of Justice, *Second Appalachian Region Prescription Opioid Strikeforce Takedown Results in Charges Against 13 Individuals, Including 13 Physicians* (Sept. 24, 2019), https://www.justice.gov/opa/pr/second-appalachian-region-prescription-opioid-strikeforce-takedown-results-charges-against-13.

of heart palpitations after dancing at a wedding. Ex. 18 at 4. Although Ms. Hughes and her mother again identified the HPV vaccine as causal to emergency care treaters, EKG and chest x-ray were essentially normal, and she was advised to follow up with outpatient treatment. *Id*.

2015 and Beyond

From early 2015 to the present, the record establishes that Petitioner has obtained additional treatment from Dr. DeMio. In January 2015, Dr. DeMio prepared a letter similar to that penned by Dr. Flynn, noting that he was treating Ms. Hughes "for multiple diseases and disorders," including Lyme disease and "Autoimmune and Metabolic Disorders," and that because her condition could cause "extreme fatigue, pain, and brain fog," she required a limited school schedule. Ex. 10A at 44. Yet, extensive lab testing (re)conducted by Dr. DeMio in May 2015 revealed hardly any abnormal results. *Id*. at 31–48.

In August 2020, Petitioner filed a two-page medical record excerpt from the Cleveland Clinic Neurology Department, dated January 13, 2020, purportedly establishing associated diagnoses of POTS, sleep pattern disturbance, and insomnia of an unspecified type. Ex. 47, filed on Jan. 13, 2020 (ECF No. 76-1). The record did not indicate that Petitioner had undergone any kind of specialized tests that would corroborate these diagnoses, however, nor is it corroborated with any other records, and thus the probative value of this document is greatly limited. *Id*.

II. Petitioner's Expert Opinions

A. *Dr. Philip DeMio*

Dr. DeMio offered a two-page report in support of Petitioner's claim, based upon his own direct experience treating her, and it was filed at the outset of the matter. Report, dated July 30, 2016, filed as Ex. 11 (ECF No. 8-1) ("DeMio Rep.").

Dr. DeMio obtained his Bachelor of Science degree from Creighton University in 1980, and his M.D. from Case Western Reserve University in 1984. *See* CV, filed as Ex. 49 (ECF 76-8) at 1. He thereafter completed a residency in pathology at the University Hospitals of Cleveland, and Medicine and Emergency Medicine residencies at Mt. Sinai Medical Center. *Id.* at 2. His practice primarily consists of the treatment of chronic tick-borne and other infections and Autism Spectrum Disorder, plus some treatment of chronic pain or diseases. *Id.* Dr. DeMio's curriculum vitae lists several medical faculty positions he has held (although it gives no dates of service), including positions at the Cleveland Clinic Foundation, Case Western Reserve University School of Medicine, Mt. Sinai Medical Center, American College of Surgeons, and the American Heart Association, as well as certifications he holds from the American College of Emergency Physicians, and in Advanced Pediatric Life Support and Advanced Trauma Life Support for Physicians. *Id.* at 2, 3. Dr. DeMio has written articles on arthritis, gout, inflammation,

gastrointestinal issues, and nutrition, and has spoken at conferences covering topics such as chronic spine injuries and Lyme disease. *Id*. at 3.

Other special masters have noted, however, that Dr. DeMio's training and credentials do not cover the medical or scientific subjects upon which he purports to offer specialized expert opinions. *See, e.g.*, *Holt v. Sec'y of Health & Hum. Servs*., No. 05-136V, 2015 WL 4381588, at *16 (Fed. Cl. Spec. Mstr. June 24, 2015) ("[Dr. DeMio] is board certified in emergency medicine. He has no formal specialized training in ... any of the several areas [pediatrics, immunology, neurology, or gastroenterology], in which he proffered opinions. His only publications involved chapters on arthritis, gout, inflammation, and nutrition in an integrative medicine textbook"); *mot. for review den'd,* 132 Fed. Cl. 194 (2017). They have also routinely observed a lack of rigor and specificity in the opinions he offers. *Dia v. Sec. of Health & Human Servs.*, No. 14-954V, 2017 WL 2644695, at *3–4 (Fed. Cl. Spec. Mstr. May 25, 2017). As a result, special master determinations to give little weight to opinions provided by Dr. DeMio have been upheld on appeal. *Bailey Jr. v. Sec. of Health & Human Servs.*, No. 15-1417V, *mot. for rev. denied*, slip op. (Fed. Cl. Nov. 10, 2020) (denying compensation for injuries allegedly caused by flu vaccine based on conclusion that Petitioner suffered from ALS, not vaccine induced GBS); *Wyatt v. Sec'y of Health & Hum. Servs*., No. 14-706V, 2018 WL 7017751, at *22 (Fed. Cl. Spec. Mstr. Dec. 17, 2018), *mot. for review denied*, 144 Fed. Cl. 531 (2019), *aff'd,* 825 F. App'x 880 (Fed. Cir. 2020) (denying compensation because Petitioner failed to prove she suffers from a definitive vaccine-related injury or that any alleged vaccine-related injury lasted longer than the requisite six months).

Dr. DeMio's report states that Ms. Hughes was in "very good health" prior to her receipt of vaccines on August 15, 2013, but thereafter experienced a worsening course of symptoms. DeMio Rep. at 1. He references her January 2014 initial visit with him, at which time he claims to have observed on exam "emotional lability," "tender asymmetric lower extremity muscle masses," asymmetric deep tendon reflexes, mottled skin and abnormal toenails. *Id.* In response, Dr. DeMio conducted testing and "treated [Petitioner] for findings of immunologic and metabolic dysfunction." *Id*. at 2. He opines that Petitioner's health declined due to receipt of the three vaccines in August 2013, rendering her "medically disabled" on a permanent basis. *Id.*

To support this contention, Dr. DeMio's report lightly sketches a conclusory theory for how the vaccines sickened Petitioner. The vaccines she received contain "aluminum adjuvants, immunogenic microbial proteins, and microbial DNA," all of which function to "elicit intense long-lasting reactions in the body." DeMio Rep. at 2. But these vaccine components can produce "pathologic responses . . . resulting in lesions in vascular structures and to end organs, via cellular damage in many tissues." *Id*.; L. Tomljenovic et al., *Postural Orthostatic Tachycardia with Chronic Fatigue After HPV Vaccination as Part of the "Autoimmune/Auto-inflammatory Syndrome Induced by Adjuvants": Case Report and Literature Review*, J. of Investigative Med. High Impact Case Rep. 1–8 (2014), filed on Jan. 1, 2018 as Ex. 36 (ECF No. 48-2). It was Dr.

DeMio's view that such harm likely occurred here—especially given the "ruling out" of other causes as reflected by Petitioner's test results. *Id.*

Dr. DeMio specifically argued that the HPV vaccine likely played a role in Petitioner's injury. He maintained that (a) this vaccine was not adequately tested before being deemed safe for administration nationally, and (b) that it has been associated with death in pediatric cases like that of Petitioner. Finally, he disputed that somatization disorder explained Ms. Hughes's symptoms, proposing that certain of her symptoms, like muscle atrophy, or lab findings could not be explained in this manner. DeMio Rep. at 2.

B. *Dr. James Lyons-Weiler, Ph.D.*

Dr. Lyons-Weiler's expert report was the second filed on Petitioner's behalf. Report, dated December 12, 2016, filed as Ex. 20 (ECF No. 15-3) ("Lyons-Weiler Rep."). This report specifically focused on purported safety issues with the HPV vaccine, with some passing references to how it might have harmed Ms. Hughes.

As reflected in his CV, Dr. Lyons-Weiler received his B.A. from the State University of New York-Oswego, followed by a Master's degree in Zoology from the Ohio State University and a Ph.D. in ecology, evolution, and conservation biology from the University of Nevada in Reno. Ex. 21 at 1, filed December 15, 2016 (ECF No. 15-4) ("Lyons-Weiler CV"). Dr. Lyons-Weiler reports that he is the CEO and Director of "The Institute for Pure and Applied Knowledge," which (as its website indicates), is a not-for-profit organization that "help[s] investigators in their efforts to reduce human pain & suffering through biomedical and related forms of research." IPAK, http://ipaknowledge.org/ (last visited October 21, 2020). The website describes Dr. Lyons-Weiler's primary interests "in the development of prediction models of adverse outcomes of biomedical treatments, therapies, and biologic prophylatics [sic]…" *Id.* It also provides HPV vaccine information for parents and patients. IPAK, http://ipaknowledge.org/HPV-Vaccine---Information-for-Parents-and-Patients.php (last visited October 21, 2020).

Thus, as the aforementioned should make clear, Dr. Lyons-Weiler appears to have a personal interest in vaccine composition, safety, or the molecular processes by which the immune system reacts to vaccination (and the possible deleterious effects of the same). However, his training and background render him ill-equipped to offer the opinion he has fashioned for this matter, as it goes into issues relating to molecular biology and immunology in which he has no demonstrated expertise.[13] *See Bailey Jr. v. Sec. of Health & Human Servs.*, No. 15-1417V, slip op.

[13] Dr. Lyons-Weiler has also participated in numerous public interviews, available on the internet, sharing his opinions on COVID-19 and the current pandemic, and in so doing has expressed views that could be charitably deemed interesting. For example, Dr. Lyons-Weiler "explained how the coronavirus's genetic sequence—which has been publicly released by China—contains a unique 'middle fragment' encoding a SARS (sever acute respiratory syndrome) spike protein that appears, according to his genome analysis, to have been inserted into the 2019-nCoV

(Fed. Cl. Nov. 10, 2020) (sustaining decision of special master denying compensation and noting that Petitioner's expert, Dr. Lyons-Weiler, is "not a medical doctor").

Dr. Lyons-Weiler began by noting the general proposition that "vaccines can trigger autoimmune disorders," citing some items of literature in support.[14] Lyons-Weiler Rep. at 1. He then moved onto a discussion of the propensity of the HPV vaccine to injure. He allowed that certain epidemiologic studies had concluded an absence of "autoimmune safety concerns" regarding the vaccine, but maintained that "serious issues" with such studies existed. *Id.* at 1, 8, 15. He also devoted large portions of his opinion to attempting to lay out safety concerns based on purported evidence about the dangers of the HPV vaccine generally (and its manufacture more specifically) that in his view had never been adequately considered. Lyons-Weiler Rep. at 15–16.[15] Dr. Lyons-Weiler maintained that an ample set of individual case studies, or written reports compiling several case studies, showed in fact that there was a link between the HPV vaccine and "adverse neurological and immune reactions." Lyons-Weiler Rep. at 1. None, however, provide factual similarity to the facts at hand.

For example, Dr. Lyons-Weiler cited one study discussing three case reports involving rheumatic injuries like lupus or arthritis—injuries not in contention in this case. Lyons-Weiler Rep. at 2, J.M. Anaya et al., *Autoimmune/Auto-Inflammatory Syndrome Induced by Adjuvants (ASIA) After Quadrivalent Human Papillomavirus Vaccination in Columbians: A Call for Personalized Medicine*, 33(4) Clin. Exp. Rheumatol. 545–48 (2015), filed on Nov. 30, 2020 as Ex. 54 (ECF No. 90-2). Another referenced article considered 18 young women who were evaluated for "neuropathy with autonomic dysfunction," manifesting between one and 20 days post-receipt of the HPV vaccine. B. Palmieri et al., *Severe Somatoform and Dysautonomic Syndromes after HPV Vaccination: Case Series and Review of Literature*, Immunol. Res. (2016), filed on Nov. 30, 2020 as Ex. 82 (ECF No. 93-3) ("Palmieri"). Notably, however, Palmieri's authors speculated that the case study subjects had experienced a form of immune dysfunction injury termed

virus using 'pShuttle' technology. This technique can only be done in a lab, as it has never occurred naturally in nature." Press Release, APR Newswire, *Did the Internet News Program "The HighWire With Del Bigtree" Break the Coronavirus Code?* (Feb. 4, 2020) available at https://apnews.com/press-release/pr-prnewswire/ff548c99a03afb0d69bb7871f7cd4fc0 (last visited Nov. 19, 2020). He also has previously offered support for the popular misconception that vaccines can cause autism. *See e.g.*, James Lyons-Weiler, *Human Studies that Indicate Autism/Vaccine Link*, https://jameslyonsweiler.com/human-studies-that-indicate-autismvaccine-link/ (last visited Dec. 8, 2020).

[14] This is not a controversial overall point in the context of the Vaccine Program, where petitioners routinely succeed in establishing that a vaccine likely could, and did, cause a particular disease process known to be autoimmune in pathogenesis. For that reason, I do not include any discussion of the authorities offered to support this particular contention.

[15] Because the success of a Program case turns not at all on evaluation of error in vaccine manufacture or governmental approval, but instead on an intentional "no-fault" analytic inquiry specific to the claimant at issue, there is no need for lengthy consideration of such arguments. *See generally Holmes v. Merck & Co.*, 697 F.3d. 1080 (9th Cir. 2012).

"autoimmune/inflammatory syndrome induced by adjuvants, or "ASIA"—a causation theory that has been soundly, and routinely, rejected in Program cases as medically/scientifically unreliable, thus calling into question the reliability of Palmieri's conclusions more broadly.[16]

Other literature cited by Dr. Lyons-Weiler purportedly linking the HPV vaccine to injury was of similar questionable evidentiary value, especially in light of prior decisions discussing the very same items. Thus, Dr. Lyons-Weiler referenced another article involving a case study set of 53 female patients who received the HPV vaccine and then reported autonomic dysfunction thereafter, manifesting as orthostatic intolerance, fatigue, POTS, etc. Lyons-Weiler Rep. at 2; L. Brinth et al., *Suspected Side Effects to the Quadrivalent Human Papilloma Vaccine*, 62(4) Dan. Med. J. A5064 filed on Nov. 30, 2020 as Ex. 61 (ECF No. 91-2) ("Brinth"). But (as I specifically have noted in other decisions also involving the purported harmful effects of the HPV vaccine), Brinth's reliability is greatly diminished by the self-selectivity of its subjects, *all* of whom sought out treatment based on the apprehension that their symptoms were vaccine-caused, but were never compared in a case-control manner (whether to individuals who did not receive the vaccine or persons who received it but did not report symptoms). Brinth at 1, 4; *Johnson v. Sec'y of Health & Hum. Servs.*, No. 14-254V, 2018 WL 2051760, at *24 (Fed. Cl. Spec. Mstr. Mar. 23, 2018) (discussing Brinth's deficiencies). And Brinth's authors admitted they could not confirm the causal link the article explored. Brinth at 4.

Dr. Lyons-Weiler went on to propose a biologic mechanism for how any vaccine could "lead to permanent injury." Lyons-Weiler Rep. at 3. He began by describing the autoimmune process driven by molecular mimicry, or antigenic similarity, between foreign molecules and self-structures—which can in some instances result in a process whereby antibodies produced to fight the foreign invader turn on the antigenically-similar self structure. Lyons-Weiler Rep. at 3–4. An aberrant immune process proceeding in this manner would be heightened by the inclusion of adjuvants (substances that up a vaccine's immunogenicity) in the vaccine—but in particular aluminum, which Dr. Lyons-Weiler proposed could have an unpredictable impact, especially when

[16] *See, e.g.*, *Faup v. Sec. of Health & Human Servs.*, No. 12-87, WL 9313600 (Fed. Cl. Spec. Mstr. June 17, 2019) (denying entitlement and finding that Petitioner's experts failed to address established flaws in the ASIA theory), *motion for rev. denied*, 147 Fed. Cl. 445, 462–63 (Fed. Cl. 2019); *Garner v. Sec'y of Health & Human Servs.*, No. 15–063V, 2017 WL 1713184, at *8 (Fed. Cl. Spec. Mstr. Mar. 24, 2017) (observing that the ASIA theory "is, at a minimum, incomplete and preliminary—and therefore unreliable from an evidentiary standpoint"); *Johnson v. Sec'y of Health & Human Servs.*, No. 10–578V, 2016 WL 4917548, at *7–9 (Fed. Cl. Spec. Mstr. Aug. 18, 2016) (rejecting Petitioner's expert's expansive medical theory that "any adjuvant [is] capable of causing any autoimmune disease," finding it "overbroad, generalized, and vague, to the point that it could apply to virtually everyone in the world who received a vaccine containing an adjuvant and then at some time in their lives developed an autoimmune disease"); *D'Angiolini v. Sec'y of Health & Human Servs.*, 122 Fed. Cl. 86, 102 (2015) (upholding special master's "determin[ation] that ASIA does not provide[ ] a biologically plausible theory for recovery"), *aff'd*, 645 Fed. Appx. 1002 (Fed. Cir. 2016); *Rowan v. Sec'y of Health & Human Servs.*, No. 10–272V, 2014 WL 7465661, at *12 (Fed. Cl. Spec. Mstr. Dec. 8, 2014) (rejecting the ASIA theory because it "is not a proven theory" and no "persuasive or reliable evidence" supports it), *aff'd* WL 3562409 (Fed. Cl. 2015).

multiple vaccines were administered at once. *Id.* at 4, 8. Moreover, the HPV vaccine itself was understood to be far more immune-stimulative (in terms of producing antibodies) than its wild virus analog. *Id.* As a result, "an initial hyper-stimulation of the immune system plus molecular mimicry led [Ms. Hughes] to develop autoimmunity following HPV vaccination due to the combined effects of adjuvants in multiple doses of vaccines." *Id*. at 4.

The medical record in this case, Dr. Lyons-Weiler maintained, also supported the conclusion of HPV vaccine causality. He noted that Petitioner had herself attributed her symptoms to the vaccine, along with "a physician" that he does not identify. Lyons-Weiler Rep. at 6. He pointed to evidence of a single biomarker of inflammation (the BUN/Creatine ratio)[17] from testing Petitioner received in October 2013, during her hospitalization, as significant—despite the fact that her treaters at the time, like Dr. Lancaster, did not conclude from the *overall* clinical evidence and testing that she was experiencing an inflammatory disorder or inflammation-driven disease process. *Id.* at 9; *compare* Ex. 6A at 36. Dr. Lyons-Weiler also offered the opinion that (despite a total lack of diagnostic support or corroborative proof from the record) "vaccine-induced spondylosis" was a possible diagnosis, given the "array of conditions" Petitioner had experienced. *Id.* at 6–7, 9.

Finally, Dr. Lyons-Weiler opined that the timeframe in which Petitioner's symptoms manifested was medically acceptable. He specifically maintained that "[l]ong onset of autoimmunity post-vaccination has also been established in the medical literature." Lyons-Weiler Rep. at 4; M. Gatto, *Human Papillomavirus Vaccine and Systemic Lupus Erythematosus*, 32 Clin. Rheumatol. 1301–1307 (2013) ("Gatto").[18] In Gatto, six individuals who experienced the progression of non-specific symptoms to "full-blown autoimmunity" were considered. Dr. Lyons-Weiler allowed that causality could not be assumed from such a limited number of case reports, but felt that because they involved "laboratory-verified" proof of autoimmunity (in that the presence of autoantibodies was confirmed), they still had some evidentiary value. Lyons-Weiler Rep. at 5. Dr. Lyons-Weiler did not otherwise explain in any more specific fashion why

[17] An elevated BUN to creatinine measurement is evidence of blood volume depletion. *McKown v. Sec. of Health & Human Services*, No. 15-1451V, 2019 WL 4072113, at *15 (Fed. Cl. Spec. Mstr. July 15, 2019). The BUN (or "blood urea nitrogen") test is a blood test used to measure the amount of urea nitrogen in the blood. *See Blood Urea Nitrogen (BUN) Test*, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/blood-ureanitrogen/about/pac-20384821 (last visited on October 21, 2020). Urea nitrogen is a chemical waste product that is typically removed from the body through the kidneys. *Id.* A higher than normal BUN test can suggest that the kidneys or liver may not be working properly. *Id.* Creatinine is a chemical waste product produced by muscle metabolism. *See* Creatine Test, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/creatinine-test/about/pac-20384646 (last visited on October 21, 2020). Properly functioning kidneys filter creatine from the blood. *Id.* A creatine test—which measures the level of creatinine in the blood—can thus indicate kidney irregularities. *Id.*

[18] Although Gatto was cited by Dr. Lyons-Weiler in his expert report, the reference was never filed in this case despite an order to do so. *See* Order, dated Oct. 21, 2020 (ECF. No. 89).

Petitioner's initial symptoms manifestation could have taken up to two months to appear, or how the process would have become chronic, although he did make conclusory representations that "available science" suggested her overall autoimmune reactive course would last at least eight years. *Id.* at 9.

C. *Dr. Michael Miller*

Dr. Miller, a pediatric rheumatologist, has prepared three expert reports on Petitioner's behalf. Report, dated November 15, 2017, filed as Ex. 27 (ECF No. 41-2) ("First Miller Rep."); Report, dated January 12, 2020, filed as Ex. 48 (ECF No. 76-2) ("Second Miller Rep."); Report, dated August 21, 2020, filed as Ex. 50 (ECF No. 87-1) ("Third Miller Rep."). He maintains Petitioner's injury is best characterized as CRPS, although she also experienced POTS, and that both were attributable primarily to the HPV vaccine.

Dr. Miller is a Professor of Pediatrics at Feinberg School of Medicine, Northwestern University. Ex. 27 at 3. Although he identified himself as board certified in pediatric rheumatology, he could only describe himself as "board eligible" in allergy and immunology—a nonspecific designation that could cover virtually any medical professional who has not yet taken the board exams in that specialty but has familiarity with the topics from his general medical experience. First Miller Rep. at 3. Dr. Miller nevertheless reports to have treated children with both autoimmune diseases and CRPS, and has had the occasion to evaluate if such diseases were related to vaccination. *Id.*

First Report

Dr. Miller's first, three-page report was notably perfunctory.[19] Looking at the overall record, Dr. Miller specifically agreed with the notation from the Nationwide Children's Hospital record that Petitioner's overall symptoms and clinical course were consistent with CRPS—although that record does not itself contain that diagnosis for Petitioner. First Miller Rep. at 3; Ex. 5. Dr. Miller described CRPS as "neuropathy causing severe pain." *Id.* at 2. Dr. Miller's initial report made no specific reference to any other records that would substantiate this diagnostic contention.

In addition, Dr. Miller's first report opined that the HPV vaccine specifically could cause CRPS, maintaining that the vaccine had been previously associated with neurologic damage.

[19] As the docket to this case reveals, Petitioner's former counsel represented that he was in the process of obtaining this first report from Dr. Miller (which was eventually filed in November 2017) for months before its filing – and it was eventually only filed when former counsel "learned" that he had repeatedly missed deadlines I had set in this matter. It is therefore unclear why this first report, intended to remedy the deficiencies of the reports previously filed from Drs. DeMio and Lyons-Weiler, was so conclusory and succinct, given the amount of time Petitioner had for its preparation.

Although the literature Dr. Miller offered admittedly showed an extremely low likelihood of such injury, he proposed that the rarity of the event did not rebut its possibility. First Miller Rep. at 3; E. Moreira et al., *Safety Profile of the 9-Valent HPB Vaccine: A Combined Analysis of 7 Phase III Clinical Trials*, 138(2) Pediatrics 1–31 (2016), filed on Jan. 11, 2018 as Ex. 30 (ECF No. 46-3) (three subjects out of 15,000 "experienced severe neurologic disease"). Case reports also existed that associated the HPV vaccine to small fiber neuropathies or central nervous system disease. First Miller Rep. at 3; J. Kafaie et al., *Small Fiber Neuropathy Following Vaccination*, 18(1) Clin. Neuromuscular Disease 37–40 (September 2016), filed on Jan. 13, 2020 as Ex. 48AF (ECF No. 76-3) ("Kafaie"). Dr. Miller otherwise maintained that "rare individuals" were likely to experience an abnormal reaction to the HPV vaccine due to an aberrant immune response, although (due to the very rarity of their individualized response) they could not be identified in advance and hence shielded from receipt of the vaccine. First Miller Rep. at 2.

As a mechanism for how the HPV vaccine might trigger disease akin to CRPS, Dr. Miller proposed that the vaccine could elicit a B cell response causing the production of autoantibodies that (in what he described as a case of "mistaken identity") would attack self structures on the nerves—in effect, the same theory of molecular mimicry proposed by Dr. Lyons-Weiler. First Miller Rep. at 2. While this cross-reaction would, in his explanation, initiate at the site of injection, eventually the relevant autoantibodies would "travel into circulation" and injure nerves as well as cause secondary scarring harm to tissues, which he deemed fibrosis. *Id.* The damaged nerve cells would be impaired in function, resulting in "severe, persistent pain" akin to what Ms. Hughes alleges to have experienced. *Id.* But Dr. Miller did not offer anything, whether in the way of literature or other evidence, either describing CRPS consistent with his testimony, or showing how it could be deemed the product of a pathologic immune response. He otherwise found significant that Petitioner's reported onset and subsequent symptomatic course had a temporal relationship to the vaccination, deeming that alone "diagnostic for post-vaccine Adverse Event," although he made no specific argument about (i) when a person would under his theory be expected to manifest symptoms, or (ii) what about this case fit that theory. *Id.* at 1.

Second Report

Dr. Miller's next report (offered by Petitioner in reaction to Respondent's initial motion to dismiss) was even shorter than the first, although it contained a bit more substantiation for his positions and opinions. Regarding his theory that the HPV vaccine had been associated with injuries like CRPS, Dr. Miller referenced a Japanese study. Second Miller Rep. at 2, *citing* K. Ozawa et al., *Suspected Adverse Effects After Human Papillomavirus Vaccination: A Temporal Relationship Between Vaccine Administration and the Appearance of Symptoms in Japan*, 40 Drug Saf. 1219–29 (2017), filed on Jan. 13, 2020 as Ex. 48C (ECF No. 76-5) ("Ozawa"). Researchers in Ozawa observed that affected vaccine recipients reported various symptoms, most of which were ascribed to orthostatic intolerance, CRPS, and/or cognitive dysfunction. *Id.* at 9. Ozawa itself,

however, notes that CRPS occasionally develops in adolescent girls, and a questionnaire-based study performed during the same time period reported that a group of symptoms, including CRPS, which were seen in HPV-vaccinated girls, also occurred in Japanese girls with *no history* of HPV vaccination—not to mention the study's other acknowledged limitations that make it comparable in unreliability to Brinth (e.g., lack of control group, self-selection of studied subjects, etc.) *Id*.

Dr. Miller also maintained that the feelings of faintness and hypotension that Petitioner had displayed were consistent with POTS. Second Miller Rep. at 2. However, the medical record filed in this case does not confirm that Ms. Hughes ever formally received a true, substantiated POTS diagnosis apart from an "associated diagnosis" in 2020. Dr. Miller nevertheless deemed POTS another adverse event (albeit independent from the chronic-pain related problems she reports) that is associated with the HPV vaccine. Second Miller Rep. at 2; S. Blitshteyn, *Postural Tachycardia Syndrome Following Human Papillomavirus Vaccination*, 21 European J. of Neurology 135–139, filed on Jan. 13, 2020 as Ex. 48D (ECF No. 76-6) ("Blitshteyn"); *see also* Brinth. Blitshteyn was a case series following six young women who developed new onset POTS six days to two months following HPV vaccination, and concluded that the temporal association is significant but deserves further investigation for assessment of a possible causal relationship. Blitshteyn at 138.

In addition, Dr. Miller spent some time pointing out other aspects of Petitioner's medical history that he considered supportive of his theory. He re-emphasized the temporal relationship between her symptoms and vaccination, emphasizing that pre-vaccination she "did not have the combination of symptoms of the post-Gardasil Adverse Event." Second Miller Rep. at 1. He maintained that her onset of symptoms "a few weeks" after receiving the HPV vaccine was consistent with case report evidence, again referencing articles previously cited like Kafaie. *Id.* at 2. And he took direct issue with Respondent's contentions (raised in seeking dismissal) that somatization disorder was the most substantiated explanation for Petitioner's symptoms, maintaining that she did not meet the clinical criteria for that diagnosis (for example, by displaying a "persistent high level of anxiety"). *Id.*

Third Report

The final and most recent report filed by Dr. Miller is the most substantive of the three (although it displays the same foundational deficiencies characterizing his first two). Half of the report sought to bulwark Dr. Miller's prior points regarding his causation theory. *See generally* Third Miller Rep. at 5–6. To that end, Dr. Miller again reiterated his claim that literature persuasively linked the HPV vaccine to CRPS, citing some additional articles for this contention. *Id.* at 5; *see, e.g.*, S. Richards et al., *Complex Regional Pain Syndrome Following Immunization*, (0) Arch. Dis. Child. 1–3 (2012), filed Aug. 21, 2020 as Ex. 50F (ECF No. 87-7) ("Richards").

But the articles filed with Dr. Miller's third report do not reliably support his contentions. Richards, for example, discusses four individual case studies in which an adolescent allegedly experienced CRPS after receipt of the HPV vaccine. In each case, the patient subject experienced *immediate* pain and symptoms onset, followed by demonstrated pain, paresthesia, or weakness within one to two weeks—fact patterns wholly inapposite to Ms. Hughes's medical history (and the prolonged, inconsistent pattern of symptoms it reveals). Richards at 1–2. Richards's authors also seemed to place greater weight on the "painful stimulus" of vaccination itself as instigating the CRPS, rather than the subsequent antigenic/immune response—consistent with what is known about CRPS but not consistent with Dr. Miller's theory—and further noted that its four subjects were all encouraged to receive vaccines in the future, diminishing any possible conclusion that the HPV vaccine was deemed especially risky in causing CRPS. Richards at 3. In fact, one of the new articles filed by Dr. Miller along with his third report expressly *discounts* any association between the HPV vaccine and CRPS. *See* F. Huygen et al., *Investigating Reports of Complex Regional Pain Syndrome: An Analysis of HPV-16/18-Adjuvented Vaccine Post-Licensure Data*, 2 EBioMedicine 1114–21 (2015), filed on Aug. 21, 2020 as Ex. 50B (ECF No. 87-3) at 1119 ("Huygen") ("[a]ltogether, based on the outcomes of this valuation, there is not sufficient evidence to suggest an increased risk of developing CRPS following vaccination with HPV-16/18/-adjuvanted vaccine").

Dr. Miller further claimed that scientific literature similarly bulwarked the relationship between the HPV vaccine and POTS. Third Miller Rep. at 6. But he relied for this contention on a single questionnaire-based study that focused on a very small number of individuals who reported onset of a chronic ailment soon after HPV vaccination. *See* M. Martinez-Lavin et al., *HPV Vaccination Syndrome. A Questionnaire-Based Study*, 34 Clin. Rheumatology 1981–83 filed on Aug. 21, 2020 as Ex. 50H (ECF No. 87-9) ("Martinez-Lavin"). He also referenced articles previously (but unpersuasively) offered by Dr. Lyons-Weiler, like Brinth. Nothing cited by Dr. Miller was appreciably different—or more persuasive—than literature I have encountered in *many* prior cases alleging that the HPV vaccine can cause POTS. And he attempted a slight clarification of his causation theory, explaining that the initial inflammatory response instigated by vaccination generally would be sufficient to cause the nervous system to misfire in transmitting signals, later "making permanent the experience of pain" that characterizes CRPS. Third Miller Rep. at 6. But he cited no literature at all (beyond what is partially referenced above) substantiating the association between vaccination and this process—and there is little to no testing evidence from the period close in time to Petitioners' vaccination that would suggest the existence of the complained-of inflammation (as opposed to the nonspecific complaints of leg or other pain).

The second half of the third report provided a more detailed review of Petitioner's alleged injuries and how the record connected them to vaccination. First, Dr. Miller set forth a full explication of the clinical features of CRPS, noting that they can be triggered by independent autoimmune diseases (a distinguishable contention from the argument that CRPS is *itself*

autoimmune in pathogenesis—something no proof filed by Petitioner substantiates). Third Miller Rep. at 1–2; R. Harden et al., *Validation of Proposed Diagnostic Criteria (the "Budapest Criteria") for Complex Regional Pain* Syndrome, 150 Pain 2:268–74 (Aug. 2010), filed on Aug. 21, 2020 as Ex. 50c (ECF No. 87-4) (the "Budapest Criteria"). He then cited references from the record that he maintained were consistent with his favored CRPS diagnosis—although close review of those cites reveals careful selection of one-time instances consistent with individual criteria, without a treater ever tying them together as Petitioner urges. *See, e.g.*, Third Miller Rep. at 2 (citing subjective complaints to treaters of severe pain as evidence of hyperalgesia[20] to support CRPS diagnosis); Third Miller Rep. at 2 (citing Petitioner's complaints in medical record of pain due to menstruation to support CRPS diagnosis).

Dr. Miller similarly reviewed the clinical criteria for POTS, noting that Petitioner had received the diagnosis after proper testing, albeit several years after receipt of the HPV vaccine in 2013. Third Miller Rep. at 3; Ex. 47 at 1. He added that POTS has been suggested to be autoimmune, noting its association with certain specific autoantibodies. Third Miller Rep. at 2–3. But to support his contentions, Dr. Miller again cited Blitshteyn, in which only six case studies of post-HPV vaccine POTS were discussed, with three of the six having been diagnosed with small fiber neuropathy. Blitshteyn at 136. Although Blitshteyn does favor classification of POTS as autoimmune, it does not state that small fiber neuropathy is linked to POTS. *Id.* at 138.

In addition, Blitshteyn's case studies involved symptoms onset occurring no later than two months post-vaccination, and the article's author hedged in suggesting the reliability of the conclusion that the HPV vaccine was causal. Blitshteyn at 138 (temporal association between HPV vaccine and POTS "deserves further investigation for assessment of a *possible* causal relationship" (emphasis added)). *Id.* The proposition made by Dr. Miller is not new in the Program. In fact, I have heard numerous cases, all equally unpersuasive, in which Petitioner's experts attempt to connect the HPV vaccine specifically to POTS.[21] Dr. Miller did not also explain how a diagnosis obtained almost three years after vaccination could be credibly linked to that event, although it seems his argument mostly assumes that Petitioner's general course is all connected, and led to the late-arriving diagnosis.

Dr. Miller took pains as well to attempt to rebut contrary record proof that undermines Petitioner's theory and related factual contentions. Regarding treater speculation that Ms. Hughes suffered from somatization disorder, Dr. Miller reviewed more specifically the criteria for the diagnosis but deemed it inappropriate under the facts of the case, relying on the same contentions from his earlier report. Third Miller Rep. at 4. He also directly disagreed with the fact (as amply

[20] Hyperalgesia is abnormally increased nociception (pain sense); called also hyperalgia. Hyperalgesia, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=23666&searchterm=hyperalgesia (last visited Dec. 8, 2020).

[21] *See e.g., Johnson,* 2018 WL 2051760 at *8; *McKown,* 2019 WL 4072113 at *21.

illustrated by the record) that almost all of Petitioner's treaters, from August 2013 until she saw Dr. DeMio, disputed the purported role of the HPV vaccine in causing her symptoms, questioning their credentials to reach this conclusion (although his own, only cursory expertise in immunology renders him vulnerable to the same accusation). *Id.* at 6–7.

Finally, Dr. Miller attempted to substantiate his prior assertions about the reasonableness of the timeframe for Petitioner's post-vaccination onset. He claimed at least one item of literature suggested onset of "HPV syndrome"-like symptoms could begin within 24 hours of vaccination, although more commonly it would start two to three weeks post-vaccination (despite the fact that the record does not particularly document Petitioner's pain as beginning in that period). Third Miller Rep. at 6; Martinez-Lavin at 1.

Not much weight can be given to this type of questionnaire-based study, however. Martinez-Lavin's authors attempted to gather data by e-mailing three questionnaires to individuals who had reported the onset of chronic disease soon after HPV vaccination. Martinez-Lavin at 1982. But the target population was identified with the help of HPV vaccine web-blog managers, and by seeking out patients who had previously contacted the researchers after the publication of an article discussing the topic, rendering the article subject to the defect of selection bias. *Id.* ("[i]ndividuals were asked to fill-out the questionnaire only if they had *reasons to believe* that the HPV vaccination was related to the onset of their chronic illnesses" (emphasis added)). Moreover, the concept of "HPV syndrome" itself is amorphous. When discussing limitations of the study, Martinez-Lavin's authors explained that HPV vaccination syndrome bears resemblance to various ailments including but not limited to headaches, fatigue, fibromyalgia, myalgic encephalomyelitis/fatigue syndrome, and ASIA syndrome—making it virtually indistinguishable from any grouping of these symptoms. *Id.* at 1983. And Martinez-Lavin's authors acknowledged the lack of direct medical examination of its sample as a clear limitation. *Id.*

Blitshteyn, Dr. Miller maintained, also allowed for a medically-acceptable onset between six days and two months post-vaccination—a timeframe more consistent with the record proof of Petitioner's first symptoms in October 2013. However, those initial symptoms Ms. Hughes reported are not particularly consistent with POTS.[22] (For example, Ms. Hughes initially reported bilateral leg pain accompanied by tenderness to touch (Ex. 24 at 3). Later however, she reported vague symptoms that happen to overlap with those associated with POTS, such as gastrointestinal symptoms or lightheadedness.) In addition, Blitshteyn's case studies have otherwise been repeatedly criticized in the Vaccine Program as not especially probative. *See, e.g., Balasco v. Sec. of Health & Human Servs.*, 17-215V, 2020 WL 1240917, at *30 (Fed. Cl. Spec. Mstr. Feb. 14, 2020) (noting that Blitshteyn's case studies appear to group together reports of adverse events,

[22] As Blitshteyn states, "POTS is a heterogeneous disorder of the autonomic nervous system characterized by orthostatic tachycardia, other symptoms of orthostatic intolerance, and non-orthostatic symptoms such as fatigue, gastrointestinal disturbance and migraine headache. POTS primarily affects women of reproductive age with a female-to-male ratio of 5:1 and can commonly be triggered by a virus, surgery, pregnancy or trauma." Blitshteyn at 4.

many of which are non-specific symptoms, in a conclusory manner); *Johnson*, 2018 WL 2051760, at *24. Otherwise, Dr. Miller did not propose to explain how this onset would evolve into a chronic disease process.

III. Procedural History

The matter was initiated in August 2016. Prior to the filing of the Rule 4(c) Report, Petitioner had already filed the expert reports from Drs. DeMio and Lyons-Weiler. After some delay occasioned by the parties' efforts to locate records relevant to the claim, Respondent filed his Rule 4(c) Report in May 2017 contesting entitlement. ECF No. 31. I reviewed the Report, and based on its contents informed Petitioner that she would need to obtain a third expert, since I had serious misgivings about the credibility and persuasiveness of the reports offered from Drs. DeMio and Lyons-Weiler, in light of my prior Program experience as well as review of the actual reports. Docket Entry, dated July 7, 2017. To that end, I ordered Petitioner to file such a report by early September 2017. Docket Entry, dated July 31, 2017.

In the fall of 2017, I dismissed the matter after a series of orders I had issued directing the Petitioner to file a supplemental expert report were ignored. Decision, dated Sept. 29, 2017 (ECF No. 38). I also denied Petitioner's request for relief from the dismissal judgment that subsequently entered in the case. Order, dated Feb. 16, 2018 (ECF No. 58) ("Order"). But Ms. Hughes was successful in reviving the case after her appeal of dismissal to the Federal Circuit was granted. *Moczek v. Sec'y of Health & Human Servs.*, 776 F. App'x 671 (Fed. Cir. 2019). I therefore held a status conference with the parties in the summer of 2019, ordering Respondent to file expert reports by the end of October 2019 in reaction to those already filed by Petitioner. Docket Entry, dated Aug. 8, 2019.

Instead of doing so, Respondent filed a motion requesting an order to show cause why the case should not (again) be dismissed. Dismissal Motion, dated Oct. 21, 2019 (ECF No. 71). In this motion, Respondent (observing prior comments in my Dismissal Decision about the weaknesses of the claim) argued that the existing expert showing by Petitioner was simply deficient, and did not rise to the level of a *prima facie* showing for a non-Table, causation-in-fact claim. Dismissal Motion at 6–7, *citing* Decision at 11–12. In particular, Respondent highlighted my observations in the Decision that (a) the record largely did not appear to support Petitioner's claim, (b) the opinions offered by her initial two experts were unreliable or weak for other reasons, and (c) the newest report from Dr. Miller did not remedy any of the above. Dismissal Motion at 2–4.

After some additional delay, Petitioner responded to the motion. Response, dated Jan. 13, 2020 (ECF No. 75). She questioned the procedural appropriateness of Respondent's motion, suggesting it constituted a motion for summary judgment that avoided calling itself that. Response at 3. She also argued that the evidence offered in the case to date was sufficient to meet the burden

of proof set forth in the seminal Federal Circuit case *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1247 (Fed. Cir. 2005). *Id.* at 6–12.

I considered all these filings, and thereafter denied Respondent's motion. Order, dated February 19, 2020 (ECF No. 77). In so doing, I noted that (from a summary judgment perspective) Petitioner's showing was barely adequate enough to survive Respondent's motion. Order at 2–3. I also took into account the Federal Circuit's observation that Petitioner had at least succeeded in making out a reasonable basis-level case for her claim, since the objective medical records detailed her persistent efforts to obtain treatment for the symptoms she complained of, as well as the fact of vaccination. *Moczek*, 776 F. App'x at 675–76. However, I added that Respondent *could* recast his request to dismiss as one seeking a ruling on the record, and therein attempt to show in more detailed fashion (whether or not he chose to offer his own experts) that the record and expert reports filed in the matter simply did not meet Petitioner's preponderant burden of proof. Order at 3. And I reminded both parties (in keeping with the performance of my inquisitorial role as special master) that I did not expect Petitioner would ultimately succeed in establishing entitlement, for the reasons I had voiced many times prior. Order at 3–4.

Respondent took me up on my offer and moved formally for a ruling on the record in May of this year. *See generally* Mot. Petitioner opposed the motion in August, offering another supplemental report (discussed above) from Dr. Miller to support her claim. *See generally* Opp. Respondent did not file a reply, and the matter is now fully ripe for resolution.

IV. Parties' Respective Arguments

Respondent argues that Petitioner has failed to preponderantly establish that her August 15, 2013 vaccination caused the collection of symptoms she experienced thereafter. Mot. at 8. Respondent supports this contention with evidence arising from Petitioner's pre-vaccination records in which she complained of symptoms substantially similar to those she alleges were later caused by the HPV vaccine. *Id.* at 9.

Petitioner opposes dismissal, maintains that she has provided evidence establishing a prima facie case, through medical records, affidavits, and expert reports supporting her claim, and that Respondent has provided no evidence refuting or disputing the evidence set forth. Opp. at 9. Petitioner argues that she has met her burden and, as a result, the burden has shifted to Respondent to show there is an alternate causation. *Id.* Petitioner asserts that, at a minimum, Respondent should be ordered to obtain and file a rebuttal report from a qualified expert. *Id.* at 10.

V. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006). In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation."

Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d 1367, 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury.

The Federal Circuit has consistently rejected the contention that the first *Althen* prong can be satisfied merely by establishing a proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)). Rather, this prong (like the other two) requires a preponderant showing. This naturally flows from the overarching fact that Program petitioners *always* have the ultimate burden of establishing their claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and

carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the

events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd sub nom. Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Dep't of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

There are, however, situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("'[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent'") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *Lalonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not

been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

A special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Hum. Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Hum. Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

D. *Consideration of Medical Literature*

Petitioner has filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding

certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Consideration of Comparable Special Master Decisions*

In reaching a decision in this case, I have taken into account other decisions issued by special masters (including my own) involving similar injuries, vaccines, or circumstances. I also reference some of those cases in this Decision, in an effort to establish common themes, as well as demonstrate how such prior determinations impact my thinking on the present case.

There is no error in doing so. It is certainly correct that prior decisions from different cases do not *control* the outcome herein.[23] *Boatmon,* 941 F.3d at 1358–59; *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). Thus, the fact that another special master reasonably determined elsewhere, on the basis of facts not in evidence in this case, that preponderant evidence supported the conclusion that vaccine X caused petitioner's injury Y does not compel me to reach the same conclusion in *this* case. Different actions present different background medical histories, different experts, and different items of medical literature, and therefore can reasonably result in contrary determinations.

However, it is *equally* the case that special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs.,* 76 Fed. Cl. 328, 338–39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the *expertise and experience to know the type of information that is most probative of a claim*") (emphasis added). They would therefore be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions. This is especially so given that special masters not only routinely hear from the same experts in comparable cases but are also repeatedly offered the *same* items of medical literature regarding certain common causation theories. It defies reason and logic to obligate special masters to "reinvent the wheel", so to speak, in each new case before them, paying no heed at all to how their colleagues past and present have addressed similar causation theories or fact patterns. It is for this reason that prior decisions can have high persuasive value—and why special masters often explain how a new determination relates to such past decisions.[24] Even if the

[23] By contrast, Federal Circuit rulings concerning legal issues are generally binding on special masters in all cases. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014). Special masters are also bound within a specific case by determinations made by judges of the Court of Federal Claims after a motion for review is resolved.

[24] Consideration of prior determinations is a two-way street that does not only inure to the benefit of one party. Thus, I would likely take into account the numerous decisions finding no association between vaccination and autism when confronted with a new claim asserting autism as an injury and have informed such claimants early in the life of their case that the claim was not viable for just that reason. But I would *also* deem a non-Table claim asserting GBS after

Federal Circuit does not *require* special masters to distinguish other relevant cases (*Boatmon,* 941 F.3d at 1358), it is still *wise* to do so.

F. *Evaluation of Expert Credentials and Professional Competence*

It is common in Program cases for special masters to evaluate competing expert opinions when deciding non-Table claims—and that process can be very difficult when the experts are equally well-credentialed and qualified to provide the opinion offered. Under such circumstances, resolution of a claimant's success in establishing causation turns on the comparative reliability of the scientific/medical contentions each side makes, rather than a measure of each particular expert's baseline qualifications against the other. *See, e.g., D'Tiole v. Sec'y of Health & Human Servs.*, No. 15-085V, 2016 WL 7664475, at *20 (Fed. Cl. Nov. 28, 2016) (determination that causation theory was unreliable did not arise from adequacy of Petitioner's expert, who was expressly deemed well-qualified to provide the opinion given), *mot. for review den'd,* 132 Fed. Cl. 421 (2017), *aff'd*, 726 F. App'x 809 (Fed. Cir. 2018).

In other circumstances, however, weighing the probative value of an expert's opinion fairly takes into account that same expert's qualifications or professional experience. This is most obviously necessary when an expert offers an opinion that plainly exceeds his training or individual competence. *Domeny v. Sec'y of Health & Human Servs.,* No. 94-1086V, 1999 WL 199059, at * 15 (Fed. Cl. Spec. Mstr. Mar. 15, 1999) (dentist not qualified to offer diagnostic opinion on whether petitioner had experienced a neuropathy), *mot. for review den'd,* slip op., May 25, 1999 (Fed. Cl.), *aff'd*, 232 F.3d 912 (Fed. Cir. 2000). But it can even be an issue with experts who possess immense and impressive credentials, and who in prior cases may have offered reliable opinions. *See, e.g.*, *Rolshoven v. Sec'y of Health & Human Servs.,* No. 14-439V, 2018 WL 1124737, at *21 (Fed. Cl. Spec. Mstr. Jan. 11, 2018) (otherwise-competent expert with significant Vaccine Program undermined his credibility in part with constant commentary about relevant legal standards to be applied in case). This problem becomes amplified when an expert testifies often in Vaccine Act cases, repeating the same "tics" or errors before numerous special masters in case after case.[25]

receipt of the flu vaccine as not requiring extensive proof on *Althen* prong one "can cause" matters, for the simple reason that the Program has repeatedly litigated the issue in favor of petitioners.

[25] The degree to which "frequent flyer" experts pose such problems in the Vaccine Program is likely not fully apprehended by the tribunals that sit in appellate review of the decisions issued by special masters. To give but one possible example, former Special Master Millman noted that one expert who testified before her had been expert of record in nearly *40* published entitlement decisions over a ten-year period—and that he in fact justified the contradictions and opinion shifts in the large number of reports he offered in the case then before her on the fact that he was so busy with other matters. *D.G. v. Sec'y of Health & Human Servs.,* No. 11-577V, 2019 WL 2511769, at *191, n.171 (Fed. Cl. Spec. Mstr. Cl. May 24, 2019).

Given the foregoing, special masters can properly deem particular opinions subject to limited weight if the opinion exceeds the expert's background competency. *Wyatt*, 825 F. App'x at 886 (special master properly gave expert opinion from Dr. DeMio lower weight because (a) opinion was based mostly on second-hand information, and (b) expert lacked credentials to provide opinion on autoimmune or neurologic issues). In addition—and in keeping with the fact that the special masters are expressly intended to draw on their expertise in deciding Vaccine Act claims—special masters may in some circumstances take note of an expert's conduct in other cases, and how they have been received. *Yalacki v. Sec'y of Health & Human Servs.*, No. 14-278V, 2019 WL 1061429, at *33 (Fed. Cl. Spec. Mstr. Jan. 31, 2019) (expert offered same unreliable opinion about the prevalence of autoimmune reactions to vaccination that had been rejected in prior cases), *mot. for review den'd*, 146 Fed. Cl. 80 (2019).

This case presents just such circumstances—and it is why I have cited other cases in which certain experts offering opinions in this matter have been questioned in the past. I do so not to embarrass the expert, or provide a basis for ignoring the opinion—rather, my analysis herein should underscore that the opinions of the relevant experts were *not* ignored. Indeed, it is to illuminate better why the opinion might be properly amounted little probative value. Doing so is hardly arbitrary or capricious—it is in fact the polar opposite of "arbitrary" to point out that an expert in a case before me has repeatedly been chastised by my colleagues, past and present, for exceeding his expertise, or repeatedly offering an opinion lacking in scientific rigor or foundation.

G. *Determining Entitlement Via Ruling on the Record*

I am resolving this claim on the papers, rather than by holding a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Overview of HPV Vaccine Cases and Primary-alleged Injuries

I have several times evaluated claims relying in whole or substantial part on the contention that the HPV vaccine can cause injuries akin to what is alleged herein—but never have I ruled for a petitioner under such circumstances. *See*, *e.g.*, *Sullivan v. Sec'y of Health & Hum. Servs.,* No. 17-480V, slip op. (Fed. Cl. Spec. Mstr. Nov. 13, 2020) (HPV vaccine not causal of POTS, narcolepsy, chronic fatigue, small fiber neuropathy, or exacerbation of type 1 diabetes), *appeal docketed,* Dec. 14, 2020 (Fed. Cl.); *McKown v. Sec'y of Health & Hum. Servs.,* No. 15-1451V, 2019 WL 4072113 (Fed. Cl. Spec. Mstr. July 15, 2019) (HPV vaccine did not cause POTS or chronic eczema); *Johnson*, 2018 WL 2051760 (HPV vaccine not found causal of leg and joint pain, fatigue, or POTS); *Combs v. Sec'y of Health & Hum. Servs.,* No. 14-878V, 2018 WL 1581672 (Fed. Cl. Spec. Mstr. Feb. 15, 2018) (HPV vaccine not causal of vasovagal syncope).

These prior decisions contain expansive reviews of the expert opinions plus medical and scientific evidence (to the extent it exists) offered to support a connection between the HPV vaccine and these related injuries, and I will therefore not recount in great detail the basis for these holdings. As already noted, they do not mandate the outcome in this case. I merely reference them to emphasize my great familiarity with the arguments about the HPV vaccine commonly made—along with the fact that these arguments (at least as of today's date) have often lacked credible, reliable scientific/medical support. I also note that as I became more familiar with the nature of these kinds of HPV-focused claims, I saw less need for holding a hearing. *Compare Sullivan* (decided in 2020 without hearing) *with McKown* and *Johnson* (decided after hearing in 2018–19).[26] And these prior cases involve the same literature, and even the same experts. In *McKown*, for example, the petitioner also offered treater support from Dr. DeMio, who proposed the petitioner suffered from "Gardesil [sic] Syndrome," although I rejected the contention. *McKown,* 2019 WL 4072113 at *7.

Because CRPS is the primary injury embraced by Dr. Miller (Petitioner's most credible expert), some brief discussion of its features is warranted. CRPS has been defined as a "chronic and incurable condition" impacting the central nervous system. *Dixon-Jones v. Sec'y of Health & Human Servs.,* No. 14-934V, 2019 WL 7556374, at *16, 31 (Fed. Cl. Spec. Mstr. Sept. 4, 2019) (petitioner failed to show that flu vaccine caused Petitioner's CRPS); *Dorland's Medical*

[26] I also held a hearing in 2019 in a case alleging the HPV vaccine caused POTS and other nonspecific complaints (like weakness) akin to what is asserted herein, but by Petitioner's motion the case was dismissed before I had issued an entitlement determination. *Otto v. Sec. of Health & Human Servs.*, No. 16-1144V, 2020 WL 4719285 (Fed. Cl. Spec. Mstr. June 17, 2020). I noted in my dismissal decision, however, that after hearing the evidence and live expert testimony, I would not have ruled for Petitioner in the end, even if he had not asked for dismissal. *Id.* at 2.

Dictionary Online, available at https://www.dorlandsonline.com/dorland/definition?id=110437 (last visited November 17, 2020). Type 1 (called also reflex sympathetic dystrophy) often follows tissue injury, but without demonstrable nerve injury. *Id.* CRPS typically involves ongoing pain "disproportionate to any inciting event," focusing on an arm or leg and developing fairly rapidly after injury, a surgery, a stroke or a heart attack. *Dixon-Jones,* 2019 WL 7556374, at *16, 26 (a needle prick could cause CRPS); *see also* Budapest Criteria at 18. The Budapest Criteria relied upon by Dr. Miller to illustrate the basis for his proposed diagnosis or CRPS have been recognized as providing a reasonable yardstick for the condition—although diagnosing CRPS is ultimately (given the current state of medical science) dependent wholly on clinical evidence, since there is no lab testing that can substantiate it. *Dixon-Jones,* 2019 WL 7556374, at *16; *see generally* Budapest Criteria at 1.

The contention that CRPS can be vaccine-caused has been considered in prior Program cases, and has resulted in some entitlement rulings favorable to petitioners (including cases I have adjudicated), although without much in the way of analysis that could be taken into account in resolving the present case. *See,* e.g., *Garcia v. Sec'y of Health & Human Servs*., No. 18-1688V, 2020 WL 6285315 (Fed. Cl. Spec. Mstr. Sept. 24, 2020) (Respondent conceding in case before me that evidence supported claim that flu vaccine caused CRPS); *Brown v. Sec'y of Health & Human Servs*., No. 13-594V, 2014 WL 831967 (Fed. Cl. Spec. Mstr. Feb. 5, 2014) (same). In such cases, however, the Petitioner has generally demonstrated that vaccine administration *itself* precipitated trauma close-in-time to vaccination that later resulted in CRPS—not (as alleged here) that the vaccine precipitated over time a series of progressive, nonspecific symptoms. *See, e.g.*, *Garcia*, No. 18-1688, Petition, dated November 1, 2018 (ECF. No. 1) at 1 (onset within three hours of vaccination). In fact, in cases like *Garcia* the petitioner initially sought to demonstrate that he had experienced a shoulder injury related to vaccine administration, or "SIRVA"—a common Table claim in the Program involving rapid (within two days) onset of post-vaccination pain, and thus circumstances distinguishable from what the medical record shows Ms. Hughes experienced. *Id.* at 5.

By contrast, special masters who have engaged in a more detailed consideration of the science purportedly linking different vaccines to CRPS have determined that the causation theories were largely wanting. In *Dixon-Jones,* for example, Special Master Oler's decision to dismiss the claim turned in part[27] on her conclusion that the flu vaccine had not been preponderantly shown to cause CRPS. *Dixon-Jones,* 2019 WL 7556374, at *42–43. She noted that although most of what is known about CRPS associates it with direct or traumatic injury, the petitioner's theory depended

[27] The *Dixon-Jones* decision also arose from Special Master Oler's finding that the Petitioner's symptoms could not preponderantly be shown to constitute CRPS, since (a) the petitioner had not received the diagnosis, (b) petitioner's pain was better described as "widespread" or "migratory" rather than "regional," i.e. focused on one or more limbs (with the latter consistent with CRPS but not the former), and (c) petitioner's pain course waxed and waned, and therefore was not "unrelenting" as would be the case for CRPS. *Dixon-Jones,* 2019 WL 7556374, at *33–40.

on vaccine-instigated inflammation—a mechanism that the literature did not support for the condition's pathogenesis. *Id.* at *42 ("the state of literature at this time does not suggest that the systemic immune response involved in vaccination can trigger nerve damage or neuronal injury and the subsequent complex central sensitization process that eventually leads to CRPS"). She further observed that the claimant's causation theory heavily relied on the concept of cytokine activation as driving the inflammatory process—a theory that had been repeatedly rejected in disparate Vaccine Program cases. *Id.* at *43 (citations omitted).

II. Petitioner Has Not Carried Her Burden of Proof

A. *Petitioner Has Not Demonstrated on the Present Record That She Suffered from CRPS or POTS*[28]

As a threshold matter, certain injuries alleged by the Petitioner are not preponderantly supported by the record. It is well-recognized by Program precedent that determining the existence of an alleged injury is a preliminary step to conducting the *Althen* analysis in many cases—for there can be no vaccine injury claim without proof of an injury. *Broekelschen*, 618 F.3d at 1346. Here, neither CRPS nor POTS find corroboration in the record, and thus Petitioner's claims that she experienced either must fail at the outset.

First, and most importantly, the record does not support Dr. Miller's supposition that CRPS adequately characterizes Petitioner's overall basket of symptoms. Petitioner's history is not preponderantly congruent with CRPS as set forth in the diagnostic criteria filed by Dr. Miller, but instead reveals (a) some issues close-in-time to vaccination associated with a UTI or menses, followed by (b) unexplained pain two months later, the etiology of which that clinical exam and testing (which was comprehensive and included a neurologic evaluation) could not illuminate. Such a course is inconsistent with CRPS, the hallmark of which is persistent, burning pain greatly exceeding the injury believed to have precipitated it, and located "regionally" rather than systematically. Budapest Criteria at 18. And the record thereafter continued to feature an absence of corroboration of a regional pain syndrome (unless the views of obviously less-qualified medical treaters like Dr. DeMio are given weight they do not otherwise deserve).

In addition, Ms. Hughes's pain cannot be characterized at all as "unrelenting." Budapest Criteria at 18. On the contrary—Petitioner was even observed in some treater encounters, such as her November 6, 2014 visit with Dr. Li to seem well during those times when the actual exam was not being performed. Ex. 3 at 11. And none of Petitioner's actual treaters (and there were many)

[28] Dr. Lyons-Weiler's contention that Ms. Hughes may actually have suffered from spondylosis is particularly untenable, and merits no further comment. Besides his total lack of medical qualifications to offer that counter-diagnosis, it finds absolutely *no support in the medical record*, and also is not endorsed by Dr. Miller—the expert retained by Petitioner after I initially warned her counsel about the inadequacy of her existing expert opinions.

ever proposed CRPS as a possible diagnosis, despite ample chance to do so, instead offering no clear etiology. This fact does not "open the door" to Dr. Miller's diagnosis (given the absence of another firmly agreed-upon diagnostic etiology)—for it is a *petitioner's burden* to prove injury as alleged, not Respondent's to prove the negative. *K.L. v. Sec. of Health & Human Servs.*, 134 Fed. Cl. 579, 606 (Fed. Cl. 2017).

Second, the record in this case is unsupportive of POTS as a credible diagnosis. At bottom, almost no evidence has been filed to substantiate it. POTS is a form of orthostatic intolerance, often triggered upon standing up from a seated or reclined position. Cleveland Clinic, *POTS: Causes, Symptoms, Diagnosis & Treatment*, available at https://my.clevelandclinic.org/health/diseases/16560-postural-orthostatic-tachycardia-syndrome-pots (last visited Aug. 17, 2020) filed on Aug. 21, 2020 as Ex. 50D at 1. It is characterized specifically by a heart rate increase not also associated with a change in blood pressure, and is best confirmed by a tilt table test (in which the subject is strapped to a table that is slowly turned from horizontal to vertical, while heartrate and other readings are taken). *Id.*; Mayo Clinic, *Tilt Table Test*, available at https://www.mayoclinic.org/tests-procedures/tilt-table-test/about/pac-20395124 (last visited November 17, 2020); *Yalacki*, 2019 WL 1061429, at *40, n.10.

Here, Petitioner displayed none of the most common characteristics of POTS in the months immediately after vaccination, such as syncope, faintness on standing, or fatigue. The first treater to even propose it as a possibility worthy of inclusion in the diagnostic differential was Dr. Al-Huniti in March 2014—but by that time (more than six months post-vaccination) Ms. Hughes had received comprehensive diagnostic workups, with no other treaters also so suggesting or observing symptoms that might raise it a viable diagnostic proposal. Petitioner also does not appear ever to have received a tilt table test that would formally confirm the diagnosis. The incomplete January 2020 record from the Cleveland Clinic merely *asserts* the diagnosis—it does not substantiate or corroborate it. Ex. 47. Thus, it is just as likely, without more, that the record is repeating assertions about medical histories provided to treaters by Petitioner or Ms. Moczek, rather than setting forth confirmable treater diagnoses. The POTS diagnosis is not preponderantly supported by this record.

B. *Petitioner's Symptoms Have Not Been Shown to be Vaccine-Caused or Related (Althen Prong Two)*[29]

The most compelling reason for dismissal of Petitioner's case also illuminates my rationale for deciding the case without a hearing. For even if I *could* find that the HPV vaccine is capable of causing a series of nonspecific symptoms consistent with those Ms. Hughes experienced, I could

[29] I address the *Althen* prongs herein in order of their importance to my determination, rather than in their sequential order.

not also find on this record that she has preponderantly established that her symptoms were related to or caused by that vaccine, or any others she received.

The record does not suggest that Ms. Hughes began experiencing any symptoms close-in-time to vaccination that manifested the start of some immunologic-driven changes that became chronically pathologic. And no testing results she received—from October 2013, when she first presented to treaters, until the present—are consistent with her experiencing a vaccine-produced injury (for example, that which would demonstrate the presence of ongoing inflammation). Her hospitalization in October 2013 and the work-up she received at this time are particularly persuasive in suggesting petitioner had not at this time been harmed by vaccination. And although (as noted by Dr. Miller) CRPS is characterized by *continuing* pain disproportionate to any inciting event (Third Miller Rep. at 1), the record in this case reflects that Petitioner's pain was not constant and typically waxed and waned, even within the same short temporal period. *See, e.g.*, Ex. 3 at 16 (Dr. Li noted petitioner could remove tight skinny jeans off her legs without having pain) and 2 (Dr. Li noted disparity between the persistent pain reported by Petitioner and her seemingly healthy demeanor and conduct during exam).

In reaching this conclusion, I acknowledge the existence of record evidence that Petitioner *was* complaining of pain and other symptoms within a month of her receipt of the HPV vaccine. For instance, Ms. Hughes did repeatedly report to treaters persistent lower limb and back pain, headaches, fatigue, and abdominal pain. She also alleges a more immediate reaction, although such allegations find no support in the contemporaneous record. *See Pope v. Sec. of Health & Human Servs.*, No. 14-078V, 2017 WL 2460503 at *19 (Fed. Cl. Spec. Mstr. May 1, 2017) (noting that Petitioner's allegations need not be accepted based simply upon uncorroborated allegations, especially where those after-the-fact allegations are rebutted by contemporaneous proof).[30] But putting aside the subjective nature of these complaints (and specifically the fact that testing *never corroborated* an underlying disease process correctly led treaters to propose that Ms. Hughes suffered from somatization disorder), petitioner has not preponderantly established that this grouping of overall-nonspecific symptoms was likely caused by the HPV vaccine or any of the other vaccines she received in August 2013.

Petitioner can also reference little persuasive evidence that any treaters associated her complained-of symptoms with the HPV vaccine. Any providers who have so opined that actually saw her, like Drs. DeMio or Flynn, either possess significant credibility issues that make it impossible to give their views much weight, or have utterly failed to explain the bases for their

[30] I do not give significant weight to the witness statements/affidavits provided by Petitioner or Ms. Moczek, as their contentions about a purported immediate vaccine reaction are not corroborated by record proof. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

diagnostic conclusions. By contrast, a greater number of credible and competent medical providers of varied specialties (Drs. Li, Lindsay, and Lancaster) seen by Petitioner soon after the vaccinations at issue consistently *rejected* Ms. Moczek's layperson view that the HPV vaccine had likely propagated Petitioner's symptoms—and their opinions were based on actual exam and lab work.

In the face of the above, Petitioner relies on the temporal relationship of the start of her symptoms to vaccination, reasoning that (because she purports to have been in excellent health pre-vaccination) her turn of circumstances must be vaccine-caused. This sort of reasoning is rejected out of hand in the Program, however. *Moberly*, 592 F.3d at 1323 ("a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury") (citations omitted). Absent credible and probative evidence that the vaccine "did cause" her injuries, Petitioner cannot prevail merely by pointing out a change in her purported health circumstances post-vaccination.

A final, but significant, evidentiary point weighing against Petitioner on her *Althen* prong two showing are the numerous instances in the record in which treaters proposed that her symptoms might reflect somatization disorder, rather than a vaccine-related injury. Somatization disorder is defined as "[t]he process by which psychological needs are expressed in physical symptoms." *Doe v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 597, 606 n.15 (2010), *aff'd*, 656 F.3d 1343 (Fed. Cir. 2011). In other unsuccessful Program cases, treater views that somatization disorder might explain a petitioner's overall presentation are often found in the medical records. *See,* e.g., *Pless v. Sec. of Health & Human Servs.*, No. 16-271, 2017 WL 836610 at * (Fed. Cl. Spec. Mstr. Feb. 6, 2017) (treater documented in record that he was very suspicious of an element of a somatization disorder); *Floyd v. Sec. of Health & Human Servs.*, No. 10-739, 2014 WL 1392376 at *2 (Fed. Cl. Spec. Mstr. Mar. 20, 2014) (multiple treaters noting in medical record probable somatization disorder).

Here, treaters who saw Ms. Hughes in the months immediately following her August 2013 vaccinations proposed somatization disorder as a more likely explanation for her symptoms. *See, e.g.*, Ex. 6C at 30 (Dr. Lindsey indicated in the record "I feel that the underlying etiology of her symptoms is a somatization disorder and I feel strongly that she would benefit from Cognitive Behavioral Therapy"). Some treaters reached this conclusion *after* exams and other clinical tests failed to identify an alternative etiology, or (in Dr. Li's case) after personally observing a divergence between Petitioner's claimed pain symptoms and her behavior once an in-office exam had concluded. Ex. 6A at 23 (diagnostic consideration of "[a]nxiety/[m]ood disorder: This is of high likelihood given the nature of the complaints and the lack of objective findings to substantiate the complaints"); Ex. 3 at 16 (Dr. Li noting "..she [Petitioner] was wearing tight skinny jeans. When she was taking them off her legs (it was tight and required some pulling) she could do it without having pain or showing any grimacing. However, when I do light tough (just my

fingertips)… it was extremely painful enough to bring tears..."); Thus, the record establishes the possibility of somatization disorder as a reliable, evidence-based explanation for Petitioner's overall condition that was not proposed in passing.

I readily acknowledge that this record does not contain a fully-substantiated, formal diagnosis for somatization disorder, even if (contra Dr. Miller's contentions) there is ample proof of Petitioner's anxiety when displayed to treaters or discussed with them. And as special master I am not called upon (or even qualified) to make such a diagnosis myself. But it remains undisputed that several qualified medical treaters, approaching the Petitioner from different diagnostic "angles" and based on their various expertise, proposed this as a possible etiology for her symptoms. Petitioner has not rebutted their determinations or provided any persuasive reason to find the possibility unlikely (outside of Dr. Miller's *ipse dixit*), further undermining the success of her *Althen* prong two showing. *K.L.*, 134 Fed. Cl. 579, 598 ("regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case") (internal citations omitted).

C. *Petitioner Has Not Demonstrated that the HPV Vaccine Can Cause Injuries Similar to Those Complained-of in this Case (Althen Prong One)*

Besides being unable to show a cognizable, vaccine-caused injury, or that the HPV vaccine was likely responsible for her basket of symptoms, Petitioner was also unable to preponderantly demonstrate that the HPV vaccine "can cause" POTS or CRPS.

Contentions regarding POTS being caused by the HPV vaccine are more easily resolved. As stated above, I have repeatedly ruled against petitioners alleging that the HPV vaccine could cause POTS. *See e.g.*, *McKown*, 2019 WL 4072113; *Combs*, 2018 WL 1581672; *see also Otto v. Sec'y of Health & Hum. Servs.*, No. 16-1144V, 2020 WL 4719285 (Fed. Cl. Spec. Mstr. June 17, 2020) (case dismissed after hearing on claimant's request, but noting that petitioner had not successfully met his burden of proof). As I note above, these cases do not *compel* the same result herein, but they involve arguments similar to what has been put forward here, with Petitioner relying on much of the same reasoning previously rejected but without offering any new bases for reexamination of prior conclusions.

My prior determinations about the lack of demonstrated, reliable association between POTS and the HPV vaccine are the product of intensive and careful evaluation, focusing on what is known about POTS and its relationship to the immune system. POTS is most commonly *not* considered attributable to an autoimmune process interfering with the autonomic nervous system (and thus would not likely be the product of an aberrant immune response triggered by vaccination). Rather, it is thought to reflect the autonomic system functioning *properly* in response

to stressors (for example, hypovolemia, in which a person's dehydrated states produces orthostatic imbalance). *See, e.g.*, *McKown*, 2019 WL 4072113, at *52. Thus, POTS can occur in the context of a functioning autonomic nervous system.

Moreover, while it is true that some evidence has emerged in the last ten years that in rare cases POTS might *sometimes* be attributable to an autoimmune process involving anti-adrenergic antibodies (which can cause heart rate increases), this is the exception to the rule—and to date, not nearly enough is known about how this process works or what would initiate it, to draw conclusions in Program cases sufficient to meet the preponderance level of evidence.[31] Further, in none of these cases was it preponderantly established, through citation to reliable scientific evidence or expert testimony, that the HPV vaccine could cause the production of the anti-adrenergic autoantibodies posited to cause POTS in some limited circumstances.[32]

Against this backdrop, nothing offered *in this case* by Petitioner or her experts provides more recent or reliable scientific/medical evidence, in whatever form (literature, expert testimony, etc.) supporting the conclusion that the HPV vaccine might cause POTS. For example, Dr. Lyons-Weiler could only offer evidence in the form of case study-oriented association, like Brinth, which is weak and dependent on self-selected patient populations rather than scientifically-reliable studies. Further, Dr. Lyons-Weiler's critiques of epidemiologic studies that discount the HPV vaccine-POTS relationship are equally unpersuasive. Lyons-Weiler Report at 15, referencing C. Chao et al., *Surveillance of Autoimmune Conditions Following Routine Use of Quadrivalent Human Papillomavirus Vaccine*, 271 J. Internal Med. 193–203 (2012) ("Chao").[33] Chao was a peer-reviewed observational study analyzing a database comprised of the medical histories of approximately 189,000 women in California to determine whether the studied population had developed a variety of autoimmune conditions after receiving the HPV vaccine. Chao at 194. As I have previously observed, Chao is very strong evidence rebutting the contention that the HPV vaccine likely elicits *any* autoimmune diseases. *Johnson*, 2018 WL 2051760 at *25.

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[31] Another case I decided (although not involving the HPV vaccine specifically) is instructive on this point. *See Yalacki,* 2019 WL 1061429, at *18 (discussing change in medical views on the likelihood that HPV might in some cases be an autoimmune-driven condition).

[32] In *Yalacki*, the petitioner's experts proposed that an "adrenergic antibody," presumably produced in response to the hepatitis B vaccine, was the most likely mechanistic causal element in triggering Petitioner's POTS. *Yalacki*, 2019 WL 1061429 at *20. However, the literature offered to support this contention did not involve an actual measurement of the antibody in question in humans. *Id.* While the petitioner was able to offer some reliable literature exploring the possibility that *some* cases of POTS might be autoimmune-mediated, Petitioner acknowledged that more recent research moved away from autoimmunity as the most likely explanation for POTS, in the majority of individuals. *Id.* at *31.

[33] Dr. Lyons-Weiler refers to the Chao study multiple times in his expert report, but this item of literature was never filed in this case (despite my order that Petitioner do so). *See* Order, dated Oct. 21, 2020 (ECF No. 89). I have, however, in other decisions discussed Chao at length, and am thus very familiar with its findings. *See e.g.*, *McKown*, 2019 WL 4072113, at *36; *Johnson*, 2018 WL 2051760, at *15, 25; *Maciel v. Sec. of Health & Human Servs.*, No. 15-362V, 2018 WL 6259230, at *14 (Fed. Cl. Spec. Mstr. Oct. 12, 2018).

Petitioner also puts too much emphasis on case reports, or literature that depends on a curated selection of case reports like Blitshteyn. Although case studies in which a temporal correlation was observed between receipt of the HPV vaccine and POTS or comparable kinds of orthostatic intolerance are *some evidence* that should be considered as part of a special master's overall entitlement determination, they are not particularly *probative* of causation, and for that reason do not in most instances merit significant weight. *See R.V. v. Sec. of Health & Human Servs.*, No. 11-504V, 2016 WL 3882519, at *41 (Fed. Cl. Spec. Mstr. Feb. 19, 2016) ("individual patient case reports… are not, in general strong evidence of causation" (internal quotation marks omitted), *mot. for rev. denied*, 127 Fed. Cl. 136 (2016). And as noted above, many of these items of literature (e.g., Brinth or Ozawa) are facially deficient and unreliable evidence establishing a link between POTS, or other allegedly-autoimmune conditions, and the HPV vaccine.

Petitioner's showing associating CRPS with the HPV vaccine was similarly deficient, although in a somewhat less clear-cut manner. I have not previously addressed in a prior decision whether the HPV vaccine can cause CRPS, but other persuasively-reasoned decisions directly considering this issue have not been favorable to petitioners. *See Balasco*, 2020 WL 1240917, at *31 (noting that the American Autonomic Society has concluded that the data do not support a causal relationship between HPV vaccination and CRPS, POTS, or other forms of dysautonomia) (internal citations omitted). As more specifically noted in *Balasco*, an association between HPV vaccination and various symptoms such as CRPS, POTS, or SFN is cast further into doubt by the fact that, notwithstanding the assumption that all three conditions involve autonomic activity, "there is little or no substantiation of any shared pathophysiology." *Id.* Nothing offered in this case provides me with a basis for reaching a different outcome herein.

Moreover, decisions I have rendered involving the HPV vaccine and its general association with similar injuries to that alleged herein are also not supportive of Petitioner's theory that the HPV vaccine can initiate (whatever the proposed mechanism) an autoimmune response sufficient to cause *any kind* of neuropathic condition. *McKown*, 2019 WL 4072113, at *48-49 (holding that even if it was determined that a rare, neuropathic/autoimmune form of POTS could include symptoms consistent with Petitioner's skin rashes and syncope, there remained substantial deficiencies in Petitioner's theory that HPV vaccine could trigger or exacerbate such additional symptoms via an autoimmune process); *Combs*, 2018 WL 1581672, at *19 (petitioner could not substantiate her theory that she experienced vasovagal/reflex syndrome as a result of HPV vaccination, with even indirectly-relevant reliable scientific or medical evidence).

Petitioner's experts in this case were unable to offer new perspectives on the issue of HPV vaccine causation that would persuasively establish a reason for me to look anew at similar contentions. Dr. Lyons-Weiler, for example, either repeated general points about causation that come close to bromides in the Program (such as "molecular mimicry" as the mechanistic heart of

any pathologic process allegedly resulting in a vaccine-induced injury), or made contentions about the HPV vaccine's potentiality for cross-reaction due to homology (amino acid sequence or structure similarity) that I have heard, but rejected, many times before. *Sullivan v. Sec'y of Health & Hum. Servs.*, No. 10-398V, 2015 WL 1404957, at *17–18, n. 30 (Fed. Cl. Spec. Mstr. Feb. 13, 2015) (while the law does not require Petitioner to "prove" homology in a Program case, mere assertion that HPV strain shares sequences with human body such that molecular mimicry might occur resulting in injury was by itself insufficient to satisfy burden). He similarly invoked literature (such as Brinth) to which I have not given significant weight in the past.

Compounding the specific deficiencies listed above, the general credentials and qualifications of the experts in this case also harmed Petitioner's *Althen* prong one showing—especially those of Drs. DeMio and Lyons-Weiler. Neither have immunologic experience or trustworthy background in the kinds of injuries complained of herein—and Dr. Lyons-Weiler's credentials are not even medically-oriented in the first place.[34] *Duncan v. Sec'y of Health & Human Servs.*, No. 16-1367V, 2020 WL 6738118 at *2 (Fed. Cl. Spec. Mstr. Oct. 19, 2020) (noting that Dr. Lyons-Weiler is not a medical doctor but rather has a Ph.D. in ecology).

These two experts also have also been previously been criticized for espousing unreliable opinions. *See, e.g.*, *Sterling v. Sec'y of Health & Hum. Servs.*, No. 16-551V, 2019 WL 5098964, at *11 (Fed. Cl. Spec. Mstr. Aug. 27, 2019) (observing the "meandering, confusing nature" of Dr. Lyons-Weiler's reports, along with the fact that he had no demonstrated training or expertise in immunologic matters); *Kamppi v. Sec'y of Health & Hum. Servs.,* No. 15-1013V, 2019 WL 5483161, at *11 (Fed. Cl. Spec. Mstr. July 24, 2019) (giving little weight to Dr. Lyons-Weiler's opinion that "did not advance any theory" bearing on how the influenza vaccine could cause GBS 15 weeks later, and that was not otherwise bulwarked by evidence of his "background, his past research, or his area of expertise"); *Wyatt*, 2018 WL 7017751, at *22 (noting that Dr. DeMio "has been criticized by this Court in the past for testifying in cases regarding medical theories which he is not qualified to render," and finding that the opinion he offered was conclusory and unreliable). I have reached the same conclusions. *A.S. v. Sec'y of Health & Hum. Servs*., No. 16-551V, 2019 WL 5098964, at *7 n4 (Fed. Cl. Spec. Mstr. Aug. 27, 2019) (noting that Dr. Lyons-Weiler cited literature that did not support his positions, and that he appeared to be wholly unqualified to opine on the question of vaccine causation); *Wolf v. Sec. of Health & Human Services*, No. 14-342V, 2016 WL 6518581 at *16 (Fed. Cl. Spec. Mstr. Sept. 15, 2016) (finding Dr. DeMio's opinion

[34] In so maintaining, I certainly do not purport that only medical doctors may credibly testify in the Program. A Ph.D. without a medical license or degree can certainly persuasively testify on his or her area of expertise if relevant to a claim (for example, a research immunologist might credibly testify as to vaccine function). And there are physicians who lack an M.D., such as osteopaths, who nevertheless possess ample, real-world experience in treating medical conditions that renders them effective and useful experts, especially on diagnostic disputes. But an ecologist like Dr. Lyons-Weiler, with *no* demonstrated treatment background or training in immunology, cannot expect to be taken seriously as a Program expert when offering an opinion on matters of vaccine causation that facially lie well outside his actual field—and it cannot be deemed arbitrary or capricious for a special master to observe such a credential deficiency and give it probative weight in analyzing the expert's opinion.

conclusory and unsupported by reliable science and that he lacked sufficient expertise to persuasively establish how vaccine would affect Petitioner from immunologic standpoint).

Overall, Drs. DeMio and Lyons-Weiler possessed serious credibility deficiencies—as I informed Petitioner early on in the case's life, when urging her to obtain a supplemental expert. Although I have reviewed their opinions and discuss them, and have also attempted to give consideration to articles or literature referenced in their reports, these two experts overall did not offer opinions that warranted significant evidentiary weight.

Dr. Miller, by contrast, was more facially-credentialed, and he has offered reports that do arise from his immediate expertise, and which otherwise merited a more careful evaluation. But his opinion was ultimately unreliable, and/or inconsistent with the medical record in this case. In particular, it ignored, or unpersuasively attempted to rebut, record evidence that was contrary to his favored CRPS diagnosis (which, as noted above, none of Petitioner's actual treaters ever embraced). His views as a rheumatologist were also undercut by the determinations of rheumatologic workups that Petitioner actually received. Ex. 7B at 7–11; Ex 6A at 36. He offered literature like Huygen that directly undercut his arguments about CRPS and its association with the HPV vaccine. Huygen at 1114. And he has no particularized expertise in immunology that would imbue his contentions about the HPV vaccine with added heft missing from the literature or other evidence filed in this case. Indeed—Dr. Miller made other contentions about vaccine causation that he was somewhat unqualified to advance, at least in any persuasive manner. His report overall embraces a diagnosis that finds little corroboration from the medical record, and his three reports, while an improvement when compared to those Petitioner offered from her other two experts, were still not sufficient to meet the preponderant standard of proof in establishing the "can cause" prong.

D. *Petitioner Has Not Demonstrated that the Timeframe for Onset of Her Symptoms was Medically Acceptable (Althen Prong Three)*

The third *Althen* prong also does not favor Petitioner, although it presents a slightly closer question. On the one hand, there is no reliable evidence that Petitioner began to experience any symptoms arguably vaccine-related before October 2013. Those problems she encountered close-in-time to vaccination were distinguishable (for example, attributable to menses), and affirmations or sworn statements to the contrary, whether from Petitioner or Ms. Moczek, are not sufficiently corroborated by record proof to be deemed superior to what the first records from Petitioner's hospitalization reveal. Petitioner's sole credible expert, Dr. Miller, has not offered much beyond case reports, or scientific articles I have previously deemed weakly probative, like Ozawa, to support the conclusion that receipt of the HPV vaccine could begin to produce manifest clinical signs two months after its administration—especially in a record devoid of any inflammatory or immune-driven process occurring *within* that two-month timeframe.

Petitioner's POTS allegations and their timing are also questionable. POTS is not even proposed by a treater for inclusion in the diagnostic differential until six to seven months post-vaccination, with little to no evidence prior to that time of an onset (as reflected in the kind of symptoms typically associated with POTS, like syncope). In addition, Petitioner's purported POTS diagnosis[35] was obtained on *August 15, 2019*—exactly four years after her first and only HPV vaccination. Although diagnosis is distinguishable from onset, the credibility of the contention that Petitioner experienced POTS onset in a medically acceptable timeframe after vaccination is greatly undercut when it has taken years for treaters to even consider the diagnosis as a possibility given the overall record.

At the same time, however, Petitioner has offered some reliable proof consistent with her theory that the HPV vaccine could cause CRPS in a two-month timeframe. And there are some decisions in which a special master has found similar timeframes to be medically reasonable. *See, e.g.*, *Dixon-Jones*, 2019 WL 7556374 (finding expert's testimony persuasive who opined that CRPS is expected "to develop rapidly, certainly within two months, probably within a month…"). Because I have already determined that insufficient preponderant evidence was offered in this case to establish that the HPV vaccine "can cause" the kinds of symptoms Ms. Hughes complained of, or that she even likely suffered from CRPS, it is somewhat a moot point whether her symptoms began in a medically acceptable timeframe. But I allow that the issue of timeframe is a closer one than the other two prongs. Had Petitioner's theory associating CRPS and the HPV vaccine been more reliably established, the close showing on this prong would likely have been favorable to her claim as well.

III. This Case was Properly Resolved Without a Trial

In ruling on the record, I am choosing not to hold a hearing. Determining how best to resolve a case is a matter that lies generally within my discretion, but I shall explain my reasoning (especially given the likelihood of further appeals in this matter).

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters

[35] *See* Ex. 47 at 1.

are expressly empowered to resolve fact disputes without a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

In this case, no hearing was required to resolve the present claim in a manner fair to Petitioner. Although Petitioner offered three expert opinions, only one (Dr. Miller's) came from an individual with enough professional credibility and expertise to be taken seriously. But the opinions Dr. Miller's three reports set forth were deficient and scientifically unreliable, as previously discussed, thus deserving of little evidentiary weight. Accordingly, and even giving that opinion as much credit as possible, as I have attempted to do, there was not enough evidence-wise to carry the day for Petitioner—and no hearing would have increased the likelihood of a more favorable outcome.

She has also had ample opportunity to substantiate her claim. My concerns about the claim's viability arose not only from my misgivings about the quality of Drs. DeMio's and Lyons-Weiler's reports, but also from my review of the *record itself*—replete as it is with treater denials of a vaccine relationship to her symptoms, along with reasoned proposals that those same symptoms reflected somatization disorder. These concerns were brought to the attention of her counsel over *three years ago*, and prompted the filing of Dr. Miller's three reports. But those reports did not resolve the problems with her claim, and they could not persuasively or credibly rebut fact record proof that was unsupportive of her contentions. It thus cannot be said that my misgivings about the claim's strength were unexpectedly sprung on the Petitioner, or that she was deprived of the chance to make a good case for entitlement given the medical record.

The fact that Respondent offered no experts of his own did not obligate me to give Petitioners' arguments (and/or the testimony of their experts) a credence that they did not merit, or to hold a hearing. I am *never* required in any case before me to accept blindly the say-so of any expert, pro or con, simply because the other side chooses not to counter an expert position with a rebuttal opinion.[36] I was able to draw on my experience in Vaccine Act cases generally (as well as consider some relevant prior cases discussed above) to ascertain the significant limitations undermining the expert opinions. Only one of Petitioner's three experts, Dr. Miller, had baseline credibility, but even his opinion (set forth in three reports) was insufficiently substantive to be deemed preponderant. There also existed sufficient relevant decisions regarding HPV vaccine and its injury-causative capacity to aid my analysis—and those decisions strongly suggested that this case would produce the same outcome. The evidence simply did not even rise to a threshold preponderant showing that would require Respondent expert input to resolve.

[36] For example, if a petitioner called Dr. Andrew Wakefield, the discredited expert who testified in the Omnibus Autism Proceeding for the petitioners, maintaining that autism is vaccine-caused in a "new" autism injury case, I would not likely require Respondent to offer his own expert to counter Dr. Wakefield's position (absent some truly-novel research casting into doubt all that is known presently about the lack of a relationship between autism and vaccines).

Admittedly, in some cases weak evidentiary showings can still satisfy (if barely) a petitioner's preponderant burden if not countered or rebutted by the Respondent. *See, e.g.*, *Barone v. Sec'y of Health & Hum. Servs.,* No. 11-707V, 2014 WL 6834557 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (ruling on record in favor of petitioner in case alleging GBS after the flu vaccine, where Respondent did not offer expert report to rebut assertions of Petitioner's expert); *Gerhardt v. Sec'y of Health & Hum. Servs.,* No. 09-180V, 2014 WL 4712690, at *11 (Fed. Cl. Spec. Mstr. Aug. 29, 2014) (concise, undetailed expert opinion on causation offered by petitioner had not been countered by any rebutting opinion filed by Respondent). But this case does not present such circumstances, because the sufficiency of a bare evidentiary showing is more often than not a function of the nature of the claim asserted. While a claim arising from well-trod ground (such as one alleging GBS after the flu vaccine) might require a bit less scrutiny overall, this is not the case where (as here) a claimant seeks to allege an injury that has been rarely compensated, based on a theory I personally have been tasked with evaluating, but rejected, numerous times.

It cannot be disputed that Petitioner offered *some* evidence in support of her claim—and the foregoing Decision should establish that this evidence was carefully scrutinized and evaluated. But the expert reports she filed were overall too deficient to stand as reliable scientific evidence that could push Petitioner's showing across the preponderance "line," and this remained the case even after Petitioner was afforded the chance to obtain additional expert assistance. I was not compelled to give such evidence extra weight solely because it was not challenged with contrary expert opinions—the evidence offered *by itself* came nowhere close to constituting preponderant proof in Petitioner's favor.[37]

Overall, this case exemplifies precisely the kind of Vaccine Program claim that does not warrant a hearing—and keeping in mind that petitioners *always* have the ultimate burden of proof helps frame why this is so. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *see also Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard). Program claimants cannot obtain a damages award simply by arguing that they were sickened after vaccination without record evidence establishing their injury, within the *Althen* framework, and bulwarked by reliable medical or

[37] The fact that the Federal Circuit (in ruling to permit the case's reopening) observed the existence of some evidence supporting Petitioner's claim also does not compel the holding of a hearing—let alone suggest Petitioner's showing was anything close to evidentiarily preponderant. At the time I dismissed the claim, I expressly noted my conclusion that reopening the matter would likely be futile. *Moczek v. Sec. of Health & Human Servs.*, No. 16-930V, at 12, slip op. (Fed. Cl. Spec. Mstr. Feb. 16, 2018). The panel disagreed, noting that Petitioner could point to *some* record evidence of injury, and thus the claim could likely survive summary judgment (thereby undermining the conclusion that relief from judgment would be futile). *Moczek v. Sec. of Health & Human Servs.*, 776 Fed. Appx. 671, 675 (Fed. Cir. 2019). But such comments did *not* amount to a weighing of the evidence, let alone a determination that Petitioner *would* prevail based solely on the evidence allowed, whether the claim was resolved at hearing or on the record. Having now performed that evidentiary balancing/weighing task (as I am compelled to do as special master), I find the evidence in this case hardly supported holding a hearing.

scientific evidence, regardless of its form, on the capacity of the vaccine at issue to cause injury consistent with that alleged. A record like this one—that does not corroborate the claim, but rather shows *treater after treater* disputing the nature of Petitioner's complaints, while also disputing causation itself—unquestionably is unsupportive of entitlement. The length and detail of the present decision should manifest the work I have undertaken to reach my conclusions—and also should alleviate any lingering concerns that there was some fact issue or credibility determination that might have turned the tide in Petitioner's favor, had this matter been permitted to go to hearing. No such outcome was possible based on the record.

CONCLUSION

Petitioner has been provided ample opportunity to substantiate her claim with reliable evidence that the HPV vaccine can cause the sorts of injuries she alleges, and did so herein. But she has not carried her burden. The deficiency of her showing is, if anything, highlighted by the fact that Respondent did not offer his own expert opinions to undermine her case—Petitioner's showing by itself, while supported by some objective evidence, did not rise to the level of preponderance such that rebuttal expert proof was necessary to resolve the claim.

Accordingly, this claim is dismissed. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.[38]

IT IS SO ORDERED.

s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[38] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.